BUNDESPATENTGERICHT

IM NAMEN DES VOLKES

URTEIL

Verkündet am
5. September 2000
Cohnen
Justizangestellte
als Urkundsbeamtin
der Geschäftsstelle

4 Ni 33/99 (EU)
verb.
4 Ni 41/99 (EU)

(Aktenzeichen)

In der Patentnichtigkeitssache

1) der Inflow Dynamics AG, Frankfurter Ring 193 a, 80807 München, gesetzlich vertreten durch den Vorstand, Herrn Peter Albrecht, ebenda,

Klägerin zu 1),

- Prozeßbevollmächtigte: Patentanwälte Dipl.-Phys. Haft u. Koll., Franziskanerstraße 38, 81669 München, -

und der

2) Scimed Life Systems Inc., Scimed Place, Maple Grove, N.M. 55311-1566, USA, gesetzlich vertreten durch Herrn Michael Berman, 10727 Geneve Lane, Minnetonka, Minnesota 55305, USA,

Klägerin zu 2),

- Prozeßbevollmächtigte: Patent- und Rechtsanwälte Bardehle u. Koll., Galileiplatz 1, 81679 München, -

gegen

die Arterial Vascular Engineering, Inc. 3576 Unocal Place, Santa Rosa, CA 95403, USA, gesetzlich vertreten durch ihren Prasidenten, Herrn Scott Solano, ebenda,

Beklagte,

- Prozeßbevollmächtigte: Patentanwälte Dipl.-Ing. H. Zimmermann u. Koll., Rosental 7, 80331 München, -

betreffend das europäische Patent 0 417 928

hat der 4. Senat (Nichtigkeitssenat) des Bundespatentgerichts auf die mündliche Verhandlung vom 5. September 2000 unter Mitwirkung des Vorsitzenden Richters Dr. Schwendy, der Richter Dipl.-Ing. Klosterhuber, Dipl.-Ing. Haaß, Dipl.-Phys. Dr. Kraus und Müllner

für Recht erkannt:

Das europäische Patent 0 417 928 wird mit Wirkung für das Hoheitsgebiet der Bundesrepublik Deutschland im Umfang der Ansprüche 1 bis 8 für nichtig erklärt.
Die Beklagte trägt die Kosten des Rechtsstreits.
Das Urteil ist für die Klägerin zu 1) gegen Sicherheitsleistung in Höhe von DM 36.000,00, für die Klägerin zu 2 gegen Sicherheitsleistung in Höhe von DM 53.000,00 vorläufig vollstreckbar.

Tatbestand

Die Beklagte ist eingetragene Inhaberin des mit Wirkung für die Bundesrepublik Deutschland erteilten europäischen Patents 0 417 928 (Streitpatent), das am 24. August 1990 unter Inanspruchnahme der Priorität der amerikanischen Patentanmeldung US 398180 vom 24. August 2000 angemeldet worden ist. Das in der Verfahrenssprache Englisch veröffentlichte Streitpatent, das beim Deutschen Patentamt unter der Nummer 690 29 114 geführt wird, betrifft eine Einrichtung und ein Verfahren zur endovaskulären Abstützung. Es umfaßt 9 Ansprüche, von denen Patentanspruch 1 in der deutschen Übersetzung folgenden Wortlaut hat:

> "1. Endovaskuläre Abstützvorrichtung, die für eine Implantation in ein Koronar- oder anderes Blutgefäß im menschlichen Körper geeignet ist, aus einem einheitlichen Bauteil (10) besteht, das so ausgelegt ist, daß es mehrere obere und untere Spitzen (12,14) aufweist, wobei das einheitliche Bauteil auf der äußeren Oberfläche eines Katheters zusammengedrückt werden kann, um zu einem betroffenen Bereich eines Blutgefäßes befördert zu werden, und dann durch Aufpumpen des Katheters aufgeweitet werden kann, um den betroffenen Bereich eines Blutgefäßes auf einem Durchmesser zu halten, der größer ist, als wenn die Abstützvorrichtung nicht implantiert worden wäre, dadurch gekennzeichnet, daß das einheitliche Bauteil aus einem drahtähnlichen Material besteht und keine Fugen aufweist."

Wegen der unmittelbar bzw mittelbar auf Patentanspruch 1 zurückbezogenen Patentansprüche 2 bis 8 wird auf die Streitpatentschrift Bezug genommen.

Die Klägerin zu 1) stützt ihre gegen das Streitpatent im Umfang der Ansprüche 1 bis 7 gerichtete Teilnichtigkeitsklage auf mangelnde Neuheit bzw erfinderische Tätigkeit und beruft sich hierzu auf folgende Druckschriften:

(1) US 4 733 665 (K5 bzw. NK2)

(2) US 4 214 587 (K8 bzw. NK4)

(3) EP 0 177 330 A2 (K10 bzw. NK3)

(4) US 4 800 882 (K11).

Die Klägerin zu 2) stützt ihre gegen das Streitpatent im Umfang der Ansprüche 1 bis 8 gerichtete Teilnichtigkeitsklage auf unzulässige Erweiterung, mangelnde Ausführbarkeit und im übrigen ebenfalls auf mangelnde erfinderische Tätigkeit. Sie beruft sich im wesentlichen auf dieselben Druckschriften.

Die Klägerin zu 1) beantragt,

> das europäische Patent 0 417 928 mit Wirkung für das Hoheitsgebiet der Bundesrepublik Deutschland im Umfang der Patentansprüche 1 bis 7 für nichtig zu erklären.

Die Klägerin zu 2) beantragt,

> das europäische Patent 0 417 928 mit Wirkung für das Hoheitsgebiet der Bundesrepublik Deutschland im Umfang der Patentansprüche 1 bis 8 für nichtig zu erklären.

Die Beklagte beantragt,

> die Klagen abzuweisen, hilfsweise mit der Maßgabe, daß das Patent mit der in der mündlichen Verhandlung überreichten Fassung des Patentanspruchs 1 aufrechterhalten bleibt.

Sie tritt den klägerischen Ausführungen in allen Punkten entgegen und hält das Streitpatent zumindest in der hilfsweise verteidigten Fassung für bestandsfähig.

Patentanspruch 1 gemäß dem Hilfsantrag enthält folgende an den erteilten Anspruch 1 angefügte Ergänzung:

"....., the peaks (12,14) being rounded with a diameter of curvature greater than the diameter of the wire-like material".

Entscheidungsgründe

Die Klagen, mit denen die in Art II § 6 Absatz 1 Nr 1 IntPatÜG, Art 138 Absatz 1 lit a und c EPÜ iVm Artikel 54 Abs 1, 2 und Art 56 EPÜ vorgesehenen Nichtigkeitsgründe der mangelnden Patentfähigkeit, der unzulässigen Erweiterung und der unzureichenden Offenbarung geltend gemacht werden , sind in vollem Umfang begründet.

1. Das Streitpatent betrifft eine Einrichtung und ein Verfahren zur endovaskulären Abstützung. Nach übereinstimmender Auffassung aller Beteiligten handelt es sich bei derartigen Abstützungen um ein in der Fachwelt als "Stent" bezeichnetes Implantat. Solche Vorrichtungen werden nach der Beschreibung des Streitpatents im Stand der Technik dazu verwendet, nach einer perkutanen transluminalen Herzkranzgefäß-Aufdehnung das Risiko des Wiederverschlusses der betroffenen Arterie zu verringern. Diese Stents würden normalerweise im Bereich der Verletzung in das Blutgefäß eingeführt und dann aufgeweitet, um den Durchgang frei zu halten. Bei allen im Stand der Technik - zB in der US 4 733 665, der US 4 776 337 oder der EP 0 177 330 - beschriebenen Stents in Form von sogenannten Maschendrähten, seien erhebliche Schwierigkeiten aufgetreten und jeder weise seinen eigenen Prozentsatz an Thrombosen, Wiederverschlüssen und Gewebe-einwüchsen wie auch einen unterschiedlichen Grad an Schwierigkeiten bei der Entwicklung auf. Auch bereite die Anpassung an die Blutgefäßform bei einigen Stents nach dem Stand der Technik weitere Schwierigkeiten. Da zudem ihre relativ große Länge die Behandlung gekrümmter Blutgefäße erschwere und ursprünglich zumindest für die ersten drei Monate nach dem Einsetzen gerin-

nungshemmende Mittel nötig gewesen seien, hätten solche Stents als praktisches Verfahren zum Behandeln eines chronischen Wiederverschlusses in der Ärzteschaft nur geringe Akzeptanz gehabt. Es habe daher schon lange ein Bedarf an einem Stent bestanden, der ein Blutgefäß wirksam offenhalte, ohne zu einer bedeutsamen Thrombose zu führen und der zur Behandlung gekrümmter Blutgefäße und Verletzungen unterschiedlicher Länge leicht mehrfach verwendet werden könne.

2. Vor diesem Hintergrund formuliert die Streitpatentschrift die Aufgabe, einen Stent bereitzustellen, der die Beschränkungen der früheren Technik im wesentlichen beseitige, einfach und zuverlässig implantiert werden könne, nicht zu einer bedeutsamen Thrombose führe und selektiv entsprechend der anatomischen Konfiguration durch die Verletzung selbst gesteuert dimensioniert werden könne.

3. Patentanspruch 1 beschreibt dementsprechend eine Vorrichtung mit folgenden Merkmalen:

   a) Endovaskuläre Abstützvorrichtung, die für eine Implantation in ein Koronar- oder anderes Blutgefäß im menschlichen Körper geeignet ist;
   b) die Abstützvorrichtung besteht aus einem einheitlichen Bauteil;
   b1) das einheitliche Bauteil weist mehrere obere und untere Spitzen auf;
   b2) das einheitliche Bauteil kann auf der äußersten Oberfläche eines Katheters zusammengedrückt werden, um zu einem betroffenen Bereich eines Blutgefäßes befördert zu werden;
   b3) das einheitliche Bauteil kann durch Aufpumpen des Katheters aufgeweitet werden, um den betroffenen Bereich eines Blutgefäßes auf einen Durchmesser zu halten, der größer ist, als wenn die Abstützvorrichtung nicht implantiert worden wäre;
   b4) das einheitliche Bauteil besteht aus drahtähnlichem Material

b5) das einheitliche Bauteil weist keine Fugen auf.

4. a) Der angegriffene Anspruch 1 des Streitpatents ist zulässig. Sein Gegenstand ist in den ursprünglichen sowie den erteilten Unterlagen offenbart. Das insbesondere strittige Merkmal "and has no joints", das in richtiger deutscher Übersetzung "und weist keine verbindenden Elemente auf" heißt (die Übersetzung in der Streitpatentschrift ist unzutreffend) folgt aus z.B. der Figur 1 in Verbindung mit der Beschreibung Spalte 5, Zeilen 23 bis 26 und Zeilen 43 bis 53 (EP 0 417 928 A1) bzw. Figur 1, Beschreibung Spalte 5, Zeilen 22 bis 24 und Zeilen 39 bis 48 (EP 0417 928 B1). Der Gegenstand des Anspruchs 1 ist, entgegen der Auffassung der Klägerinnen, auch ausführbar, zumindest unter Hinzuziehung der Beschreibung. Hier wird insbesondere auf Sp. 5, Z. 39ff verwiesen.

Weitergehende Ausführungen erübrigen sich hierzu ebenso wie zu der (zu bejahenden) Neuheit des Gegenstands des Anspruchs 1, da dieser Gegenstand nicht auf einer erfinderischen Tätigkeit beruht.

Das Merkmal "no joints" bzw. "keine verbindenden Elemente" ist nach Auffassung des Senats dabei so auszulegen, daß zwischen den einzelnen geraden Segmenten (16 in Figur 1) des Stents keine irgendwie gearteten Verbindungsstreben vorgesehen sind und daß der Stent aus einem Endlosmaterial besteht, so wie es der Spalte 5, Zeilen 39 bis 48 der Streitpatentschrift entnehmbar ist.

Aus (3) ist ein Stent (endovaskuläre Abstützvorrichtung) bekannt, der für eine Implantation in ein Koronar- oder anderes Blutgefäß im menschlichen Körper geeignet ist (Seite 1), aus einem einheitlichen Bauteil (Figur 1) besteht, das so ausgelegt ist, daß es mehrere obere und untere Spitzen (13 in Figur 1) aufweist, wobei das einheitliche Bauteil im Inneren eines Katheters zusammengedrückt werden kann, um zu einem betroffenen Bereich eines Blutgefäßes befördert zu werden (Seite 3 und Seite 6, 2. Absatz) und dann durch Ausstoßen aus dem Katheter aufgeweitet werden kann, um den betroffenen Bereich eines Blutgefäßes

auf einem Durchmesser zu halten, der größer ist als wenn die Abstützvorrichtung nicht implantiert worden wäre (Seite 5, le Absatz). Das einheitliche Bauteil besteht dabei aus drahtähnlichem Material (Seite 5 mittlerer Abs., Patentanspruch 1).
Von diesem Stand der Technik unterscheidet sich der Gegenstand des Anspruchs 1 dadurch, daß beim Stent nach Anspruch 1 der Draht an seinen Enden nicht mit einer Muffe verbunden ist, sondern aus einem Endlosdraht besteht und daß er am Einsatzort durch Aufpumpen eines Katheters aufgeweitet wird und nicht wie der Stent nach (3) nach Ausdrücken aus dem Katheter auf einen vorgegebenen Durchmesser selbst expandiert.
Der Durchschnittsfachmann, an den sich die vorliegende Lehre richtet, ist der mit der Entwicklung und Herstellung von Prothesen und Vorrichtungen für die Gefäßchirurgie, insbesondere Stents, befaßte Techniker, der selbstverständlich die einschlägigen Materialien und deren Eigenschaften genau kennt, und der bezüglich medizinischer Probleme mit einem Gefäßchirurgen zusammenarbeitet.

Wenn dieser Fachmann bei dem aus (3) bekannten Stent, der aus einem selbstexpandierenden Material gefertigt ist, feststellt oder wenn seitens des Chirurgen an ihn herangetragen wird, daß es zu Schwierigkeiten beim Einsetzvorgang kommt, weil, wie die Beklagte ausführte, der Stent beim Ausschieben ungleichmäßig expandiert oder nicht den erforderlichen Durchmesser einnimmt, so wird er nach Lösungen suchen. Zu allererst wird er dabei das weitere noch bekannte Prinzip (vgl. z.B. (4), (1)), nach dem Stents am Einsatzort z.B. mittels eines Ballons aufgeweitet werden, heranziehen und auf seine Eignung untersuchen. Er wird also das Prinzip Stents am Einsatzort mittels eines Ballonkatheters auf den erforderlichen Durchmesser aufzuweiten, auf den Gegenstand nach (3) übertragen. Das bedeutet lediglich, den bekannten Stent aus einem entsprechenden Material herzustellen, das z.B. - statt federnd ausgelegt zu sein - plastisch verformbar ist. Dazu ist er ohne weiteres aufgrund seines Fachwissens in der Lage - zumal er auch beim Gegenstand des Anspruchs 1 des Streitpatents die spezielle Materialauswahl aufgrund seiner Kenntnisse treffen muß.

Der Fachmann ist nach Überzeugung des Senats, entgegen der Auffassung der Beklagten, ohne weiteres in der Lage, im Bedarfsfall von dem einen geschilderten Stent-Prinzip zum anderen überzugehen, was insbesondere durch die Druckschrift Radiology, Februar 1987, Seite 482, linke Spalte, 1. Abs. belegt wird. Danach wurde bei einem selbstexpandierenen Stent nach dem Einbringen zusätzlich noch eine Ballonaufweitung durchgeführt.

Keinerlei Probleme bereitet dem Fachmann auch das Weglassen der Muffe 11 beim Ausführungsbeispiel des Stents nach (3) und dessen Ausbildung aus einem Endlosdraht- (Ring), zumal die verallgemeinernde Lehre von Anspruch 1 in (3) bereits von einem Draht, der in einer geschlossenen Zick-Zack-Form gebogen ist, spricht und kein separates Verbindungselement, wie eine Muffe oder dergleichen, erwähnt.

Somit beruht der Gegenstand des Anspruchs 1 insgesamt gesehen nicht auf einer erfinderischen Tätigkeit.

Daran würde auch die Auslegung des Anspruchs 1 (insbesondere des Begriffs "no joints") der Beklagten, die einen Endlosdraht als Ausgangsmaterial nicht umfaßt sehen will, nichts ändern weil, wie in den vorstehenden Ausführungen implizit bereits enthalten ist, auch diese Ausführungsform nicht auf einer erfinderischen Tätigkeit beruht.

b) Die angegriffenen Unteransprüche 2 bis 8, für die kein selbständiger Schutz geltend gemacht wurde, teilen das Schicksal des Anspruchs 1. Im übrigen ist der Gegenstand des Anspruchs 2 aus (3), Seite 5 mittlerer Abs. bekannt. Der Gegenstand des Anspruchs 3 betrifft eine naheliegende Ausgestaltung, Anregungen dazu liefert (4), insbesondere Patentanspruch 3.
Die Gegenstände der Ansprüche 4, 5 und 7 betreffen handwerkliche Ausgestaltungen, die sich nach dem jeweiligen Einsatzfall richten und somit nichts Erfinderisches enthalten.

Der Gegenstand des Anspruchs 6 unterscheidet sich vom Gegenstand der Druckschrift (3) nur durch das andere Prinzip der Stentaufweitung am Einsatzort. Zu diesem Unterschied wurde bereits in Verbindung mit Anspruch 1 Stellung genommen, so daß hierauf verwiesen wird.

Der Gegenstand des Anspruchs 6 ist aus (3), vgl. insbesondere Figur 1 mit zugehöriger Beschreibung, bekannt.

5. Der Patentanspruch 1 gemäß Hilfsantrag unterscheidet sich von demjenigen gemäß Hauptantrag durch das zusätzliche Merkmal "the peaks (12, 14) being rounded with a diameter of curvature greater than the diameter of the wire-like material" bzw. in deutscher Übersetzung
" daß die Spitzen (12, 14) gerundet sind mit einem Krümmungsdurchmesser der größer ist als der Durchmesser des drahtähnlichen Materials ".

Dieser Anspruch ist unzulässig. Das genannte Merkmal entstammt, auch nach den Ausführungen der Beklagten, allein der Zeichnung. Lediglich gezeichnete Merkmale, die in der Beschreibung und den Patentansprüchen nicht erwähnt sind, sind dann als erfindungswesentlich offenbart anzusehen, wenn der zuständige Fachmann sie am Anmeldetag auch ohne Erwähnung in Beschreibung und Anspruch als zur Erfindung gehörend erkennt (Schulte, PatG, 5. Auflage § 35 Rdn 164). Das ist hier jedoch nicht der Fall. Hier geht das gezeichnete Merkmal neben den beschriebenen und gezeichneten Merkmalen unter, so daß darauf kein Anspruch gerichtet werden kann (vgl. Schulte, wie oben). Weitere Ausführungen hierzu erübrigen sich jedoch, denn das genannte Merkmal ist aus (3) (vgl. Seite 5, letzter Absatz und Patentansprüche 4 und 7) bekannt.

Auf Seite 5 letzter Absatz ist als Krümmungsdurchmesser für die Spitzen 0,4 cm (bzw. ein Radius von 0, 2 cm) angegeben und als Drahtdurchmesser 0, 046 cm (bzw. 0, 018 inch) genannt. Damit ist die in Anspruch 1 genannte Bedingung er-

fällt und zwar auch dann, wenn es sich, wie die Beklagte meint, bei der Maßangabe in (3) um "mm"-Angaben anstatt "cm"-Angaben handeln müßte.

Die Unterschiede zum Stand der Technik nach (3) sind demnach dieselben wie beim Anspruch 1 nach Hauptantrag. Der Gegenstand dieses Anspruchs 1 beruht daher aus denselben Gründen wie zum Anspruch 1 nach Hauptantrag ausgeführt, nicht auf einer erfinderischen Tätigkeit.

Bezüglich der Unteransprüche wird auf die vorstehenden Ausführungen unter 4.) b) verwiesen.

6. Die Kostenentscheidung beruht auf § 84 Abs 2 PatG iVm § 91 Abs 1 Satz 1 ZPO, der Ausspruch zur vorläufigen Vollstreckbarkeit auf § 99 Abs 1 PatG iVm § 709 ZPO.

Dr. Schwendy Klosterhuber Haaß Dr. Kraus Richter Müllner ist wegen Urlaubs gehindert, zu unterschreiben.

Dr. Schwendy

Pr

United States Patent [19]

Palmaz

[11] Patent Number: 4,739,762

[45] Date of Patent: Apr. 26, 1988

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

[75] Inventor: Julio C. Palmaz, San Antonio, Tex.

[73] Assignee: Expandable Grafts Partnership, San Antonio, Tex.

[21] Appl. No.: 923,798

[22] Filed: Nov. 3, 1986

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 796,009, Nov. 7, 1985.

[51] Int. Cl.⁴ A61M 29/00

[52] U.S. Cl. 128/343; 604/104; 604/96; 623/1

[58] Field of Search ..... 604/93, 49, 343, 97; 623/2; 128/344, 343, 1 R

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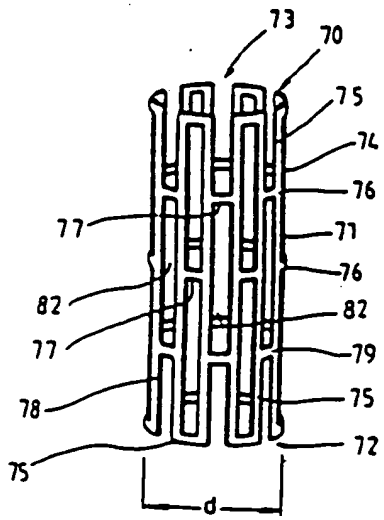
Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Gene B. Kartchner
Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

An expandable and deformable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a thin-walled tubular member having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular member.

43 Claims, 2 Drawing Sheets



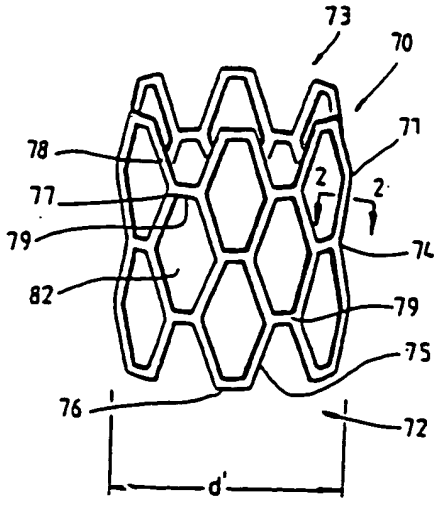


Fig. 2

Fig. 1B

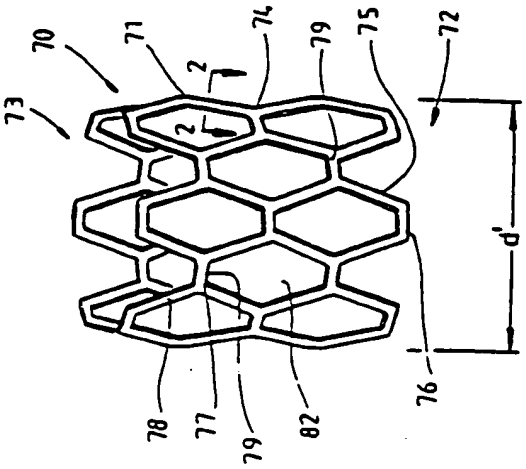


Fig. 1A

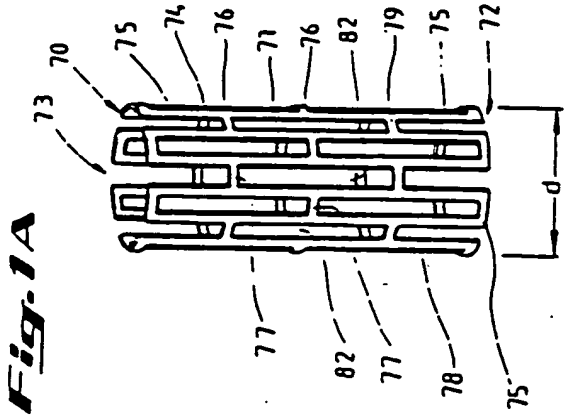
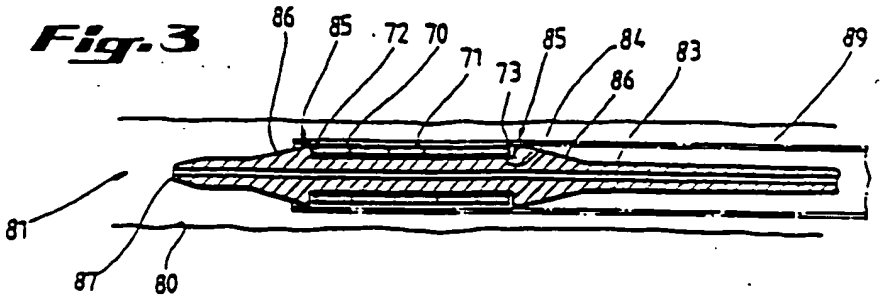


Fig. 3



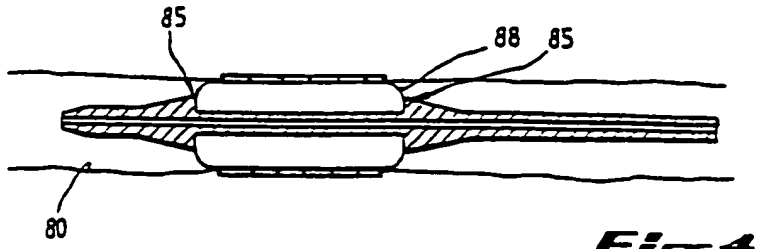
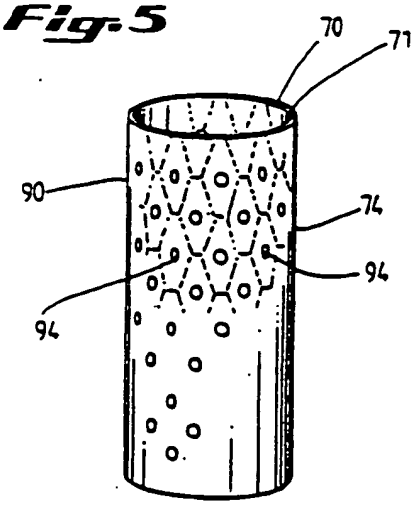


Fig. 4

Fig. 5



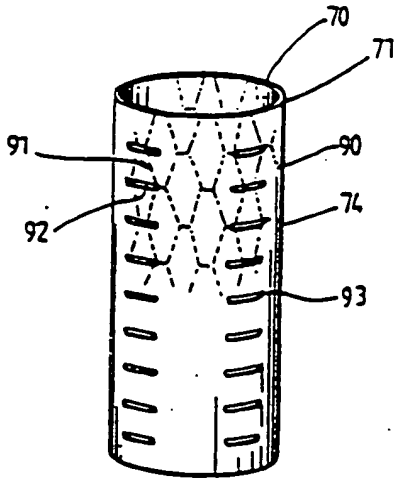


Fig. 6

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part of Applicant's co-pending application Ser. No. 06/796,009 filed Nov. 7, 1985 entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART.

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs: helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermined the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catherization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendar-

terectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; the tubular shaped member having a first diameter which permits intraluminal delivery of the thin-walled tubular member into a body passageway having a lumen: and the tubular member having a second, expanded diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular shaped member may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member. An additional feature of the present invention is that the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter. A further feature of the present invention is that the tubular shaped member may have a biological inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a prosthesis within a body passageway. The method of the present invention comprises the steps of: utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; disposing the prosthesis upon a catheter; inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

A further feature of the present invention is that the portion of the catheter in contact with the prosthesis may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots. Another feature of the present invention is that each slot may have first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable and deformable, thin-walled tubular prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prosthesis.

The expandable intraluminal vascular graft, method for implanting a prosthesis within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of

stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2-2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B; and

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION:

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the presen: invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support: (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers: (3) reinforcement of cathether created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" emcompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" emcompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed

intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired. Use of the term "slot" encompasses an opening whose length is substantially greater than its width, such as an elongated oval opening.

The foregoing described construction of graft, or prothesis, 70 permits graft, or prothesis, 70 to be expanded uniformly, and outwardly, into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prothesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prothesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described; whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prothesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prothesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, of prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then expanded and deformed by expanding the, expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80 in excess of that required to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiment shown and described, as obviously modifications and equivalents will be apparent to one skilled in the art. For example, the means for expanding the prosthesis or graft could be a plurality of hydraulically actuated rigid members disposed on a catheter, or a plurality of angioplasty balloons could be utilized to expand the prosthesis or graft. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I claim:

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a thin-walled, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

2. The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prosthesis, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prosthesis and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

5. The method of claim 4, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

6. The method of claim 5, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

7. The method of claim 1, wherein the thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby the expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of the thin-walled tubular member does not cause a rupture of the body passageway.

8. The method of claim 7, wherein the thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

9. The method of claim 1, wherein the thin-walled tubular member is provided with a biologically inert coating on the outer surface of the thin-walled tubular member.

10. The method of claim 9, wherein the coating is provided with a means for anchoring the prosthesis to the body passageway.

11. The method of claim 10, wherein the means for anchoring is the coating being provided with a plurality of radially, outwardly extending projections for engagement with the body passageway.

12. The method of claim 9, wherein the coating is provided with a plurality of openings to allow communication between the body passageway and the interior of the thin-walled tubular member.

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

14. The expandable intraluminal vascular graft of claim 13, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

15. The expandable intraluminal vascular graft of claim 14, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

16. The expandable intraluminal vascular graft of claim 13, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

17. The expandable intraluminal vascular graft of claim 13, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

18. The expandable intraluminal vascular graft of claim 13, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

19. The expandable intraluminal vascular graft of claim 13, wherein the tubular member has a biologically inert coating on the wall surface.

20. The expandable intraluminal vascular graft of claim 19, wherein the coating includes a means for anchoring the tubular member to the body passageway.

21. The expandable intraluminal vascular graft of claim 20, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

22. The expandable intraluminal vascular graft of claim 19, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

24. An expandable prosthesis for a body passageway, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

25. The expandable prosthesis for a body passageway of claim 24, wherein the tubular member has a biologically inert coating on the wall surface.

26. The expandable prosthesis for a body passageway of claim 25, wherein the coating includes a means for anchoring the tubular member to the body passageway.

27. The expandable prosthesis for a body passageway of claim 26, wherein the anchoring means is a plurality of radially, outwardly extending projections formed on the coating.

28. The expandable prosthesis for a body passageway of claim 25, wherein the coating has a plurality of openings therein to allow communication between the body passageway and the interior of the tubular member.

29. The expandable prosthesis of claim 24, wherein the the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of the tubular member, whereby at least one elongate member is formed between adjacent slots.

30. The expandable prosthesis of claim 29, wherein each slot has first and second ends, and the first and second ends of each slot are disposed intermediate the first and second ends of adjacent slots along the longitudinal axis of the tubular member.

31. The expandable prosthesis of claim 24, wherein the tubular member does not exert any outward, radial force while the tubular member has the first or second, expanded diameter.

32. The expandable prosthesis of claim 24, wherein the slots have a substantially rectangular configuration when the tubular member has the first diameter; and the slots have a substantially hexagonal configuration when the tubular member has the second, expanded diameter.

33. The expandable prosthesis of claim 24, wherein the slots have a configuration which is substantially a parallelogram after the tubular member has been expanded and deformed into the second expanded diameter.

34. The expandable prosthesis of claim 24, wherein the outside of the wall surface, of the tubular member is a smooth surface, when the tubular member has the first diameter.

35. An apparatus for intraluminally reinforcing a body passageway, comprising:

an expandable and deformable, thin-walled tubular prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the prosthesis; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prosthesis on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable, tubular prosthesis.

37. An apparatus for expanding the lumen of a body passageway comprising:

an expandable and deformable thin-walled intraluminal vascular graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the graft; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular graft on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular graft is expanded and deformed radially outwardly into contact with the body passageway.

38. The apparatus of claim 37, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable intraluminal vascular graft.

39. The method of claim 1, wherein tantalum is utilized for the tubular member.

40. The expandable intraluminal vascular graft of claim 13, wherein tantalum is utilized for the tubular member.

41. The expandable prosthesis of claim 24, wherein tantalum is utilized for the tubular member.

42. The apparatus of claim 35, wherein tantalum is utilized for the tubular prosthesis.

43. The apparatus of claim 37, wherein tantalum is utilized for the intraluminal vascular graft.

* * * * *

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United States Patent [19]

Palmaz

[11] Patent Number: 5,102,417

[45] Date of Patent: Apr. 7, 1992

[54] **EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT**

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[73] Assignee: Expandable Grafts Partnership, San Antonio, Tex.

[21] Appl. No.: 174,246

[22] Filed: Mar. 28, 1988

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 923,798, Nov. 3, 1986, Pat. No. 4,739,762, which is a continuation-in-part of Ser. No. 796,009, Nov. 7, 1985, Pat. No. 4,733,665.

[51] Int. Cl.[5] A61M 5/00; A61F 2/02

[52] U.S. Cl. 606/195; 604/8; 604/96; 604/282; 623/11

[58] Field of Search 128/343, 344; 604/93, 604/49, 282, 343, 97, 8, 283; 623/1, 12, 11; 606/191-195, 108

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—Mark Bockelman
Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

A plurality of expandable and deformable intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The grafts may be thin-walled tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members, and adjacent grafts are flexibly connected by at least one connector member.

36 Claims, 3 Drawing Sheets

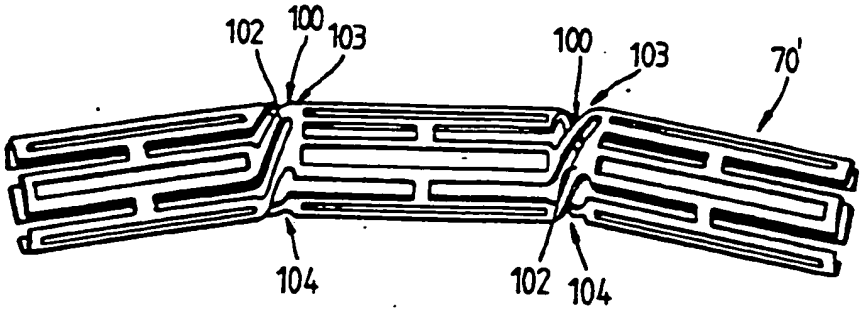


FIG.2

FIG.1B

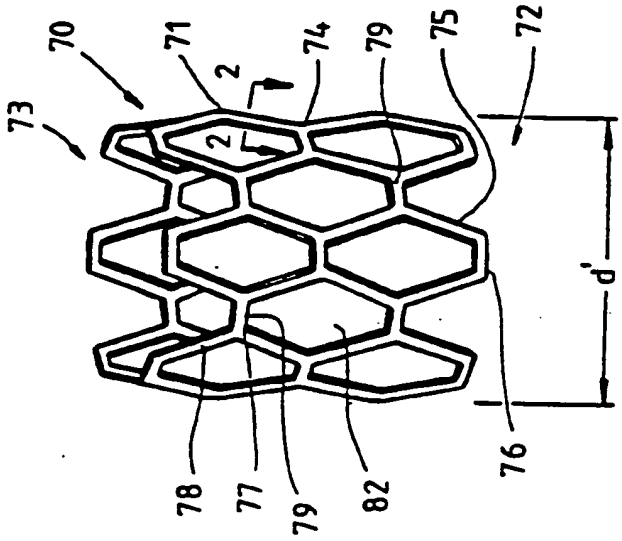


FIG.1A

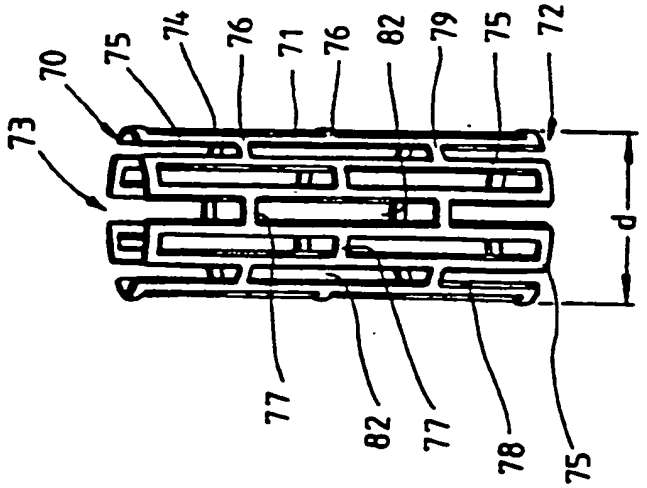
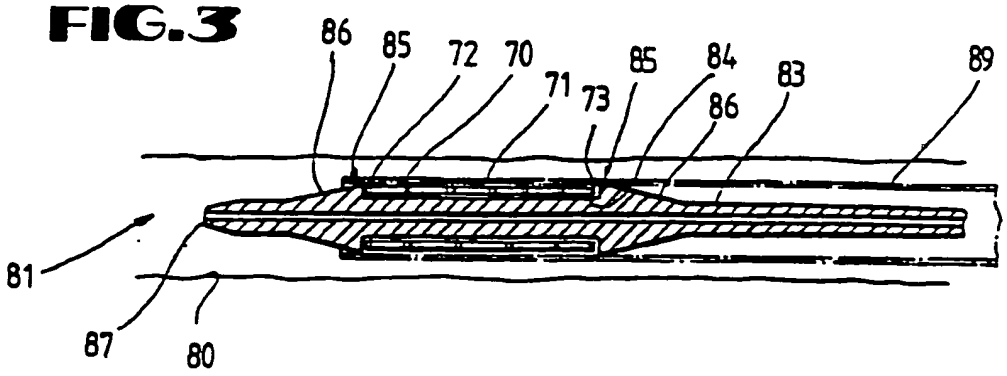


FIG.3



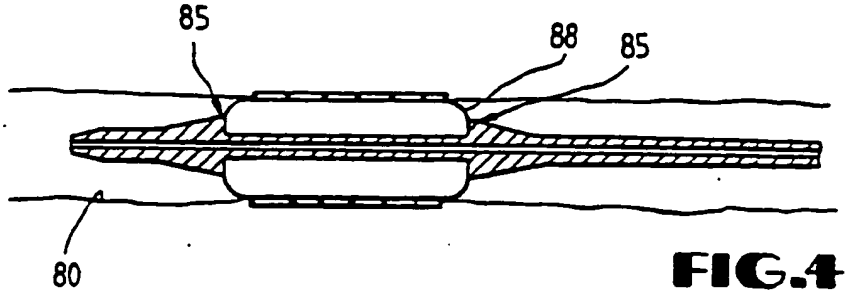
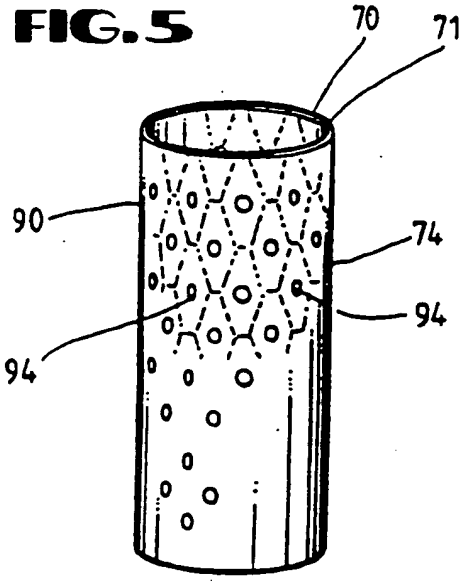


FIG.4

FIG.5



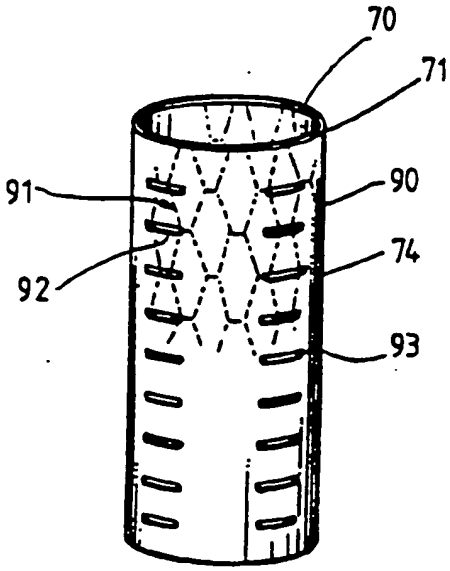


FIG.6

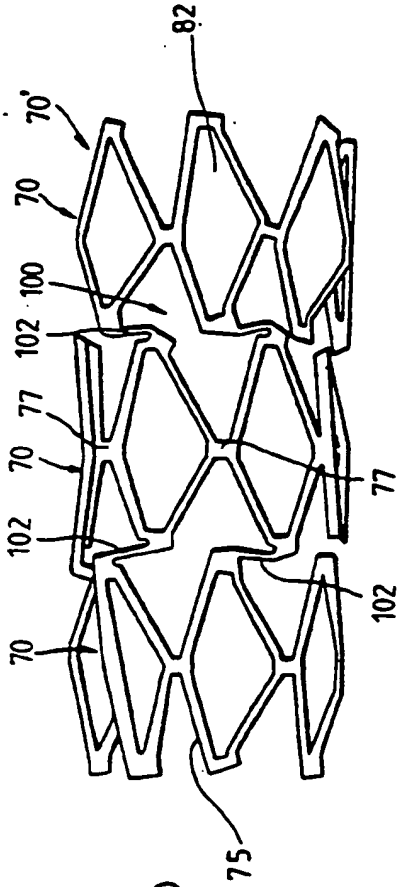


FIG.10

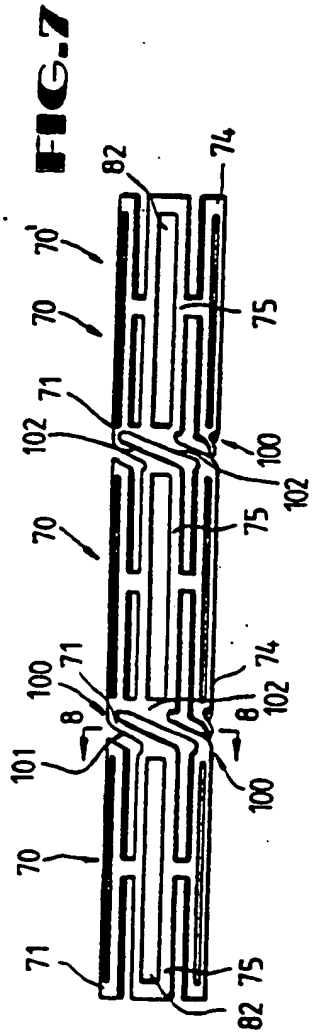


FIG.7

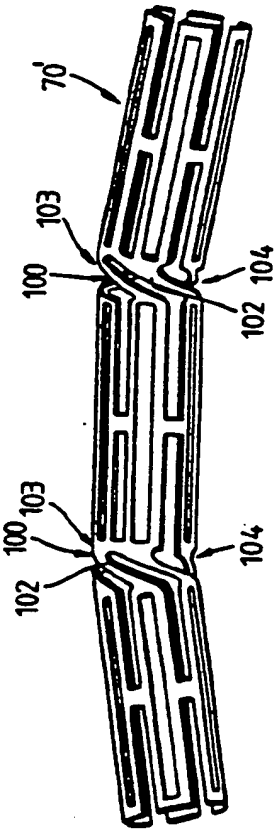


FIG.9

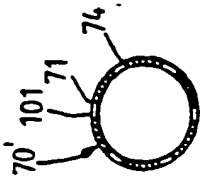


FIG.8

EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT

RELATED APPLICATION

This application is a continuation-in-part application of Applicant's co-pending application, Ser. No. 923,798 now U.S. Pat. No. 4,739,762, filed Nov. 3, 1986, which application is a continuation-in-part of Applicant's co-pending application, Ser. No. 06,796,009 now U.S. Pat. No. 4,733,665 filed Nov. 7, 1985, entitled Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft.

FIELD OF THE INVENTION

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

DESCRIPTION OF THE PRIOR ART

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that

the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty

of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location and prevents rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a plurality of thin-walled tubular members having first and second ends and a wall surface disposed between the first and second ends, the walls surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member; at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; each tubular member having a first diameter which permits intraluminal delivery of the thin-walled tubular members into a body passageway having a lumen; and the tubular members having a second, expanded diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular shaped members may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members. Another feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members. An additional feature of the present invention is that at least one connector member may be a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for implanting a plurality of prostheses within a body passageway. The method of the present invention comprises the steps of: disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other; disposing a plurality of connected prostheses upon a catheter; inserting the prostheses and catheter within the body passageway by catheterization of the body passageway; and providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prostheses with a force in excess of the elastic limit of the portion of the at least one prostheses, to implant the prostheses within the body passageway.

A further feature of the present invention is that the portion of the catheter in contact with the prostheses may be collapsed, and the catheter removed from the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that a thin-walled tubular member may be utilized as each prosthesis, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member. Another feature of the present invention is that the slots may be uniformly and circumferentially spaced from adjacent slots and the slots may be uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

Another feature of the present invention is that the at least one connector member may be disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent prostheses. A further feature of the present invention is that the at least one connector member may be disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular member. A further feature of the present invention is that the at least one connector member may be formed as a thin-walled, spiral member, coplanar with adjacent tubular members.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable and deformable tubular prostheses on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable and deformable tubular prostheses.

The expandable intraluminal vascular graft, method for implanting a plurality of prostheses within a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; permits expansion of the graft to a variable size dependent upon conditions within the body passageway; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2—2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B;

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;

FIG. 7 is a front view of another embodiment of a graft or prosthesis in accordance with the present invention;

FIG. 8 is a cross-sectional view of the graft, taken along line 8—8 of FIG. 7.

FIG. 9 is a perspective view of the graft of FIG. 7, wherein the graft has been bent or articulated; and

FIG. 10 is a perspective view of the graft of FIG. 7, after the graft has been expanded and deformed.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of catheter created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d' is variable in size and

dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, in a controlled manner into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4), should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed into the configuration of FIG. 1B, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prothesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prothesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prothesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any out-

ward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, the methods and apparatus of the present invention will be described in greater detail. Once again, it should be understood that the methods and apparatus of the present invention are useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 includes means for mounting and retaining 85 the expandable intraluminal vascular graft, or prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. Preferably, the mounting and retaining means 85 comprises retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. Preferably, as seen in FIG. 3, retainer ring members are formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon TM sheath 89, which is pulled away from prosthesis, or graft, 70, prior to expansion of the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is, controllably expanded and deformed to the second diameter, d', and the second, expanded diameter, d', is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that required to resist radial callapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid,

multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert or biologically compatible coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon TM, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area. Examples of biologically compatible coatings 90 would include coatings made of absorbable polymers such as those used to manufcture absorbable sutures. Such absorbable polymers include polyglycoides, polylacoides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating 90 is absorbed, or dissolves, the drug would be slowly released into the body passageway 80.

Turning now to FIGS. 7–10, an expandable intraluminal vascular graft, or prosthesis, 70' is shown for implantation in curved body passageways 80, or for use in elongated sections of body passageway 80, when a prosthesis, or graft, 70' is required which is longer than the grafts, or prostheses, 70 of FIG. 1A. Identical reference numerals are used throughout FIGS. 7–10 for elements which are the same in design, construction, and operation, as those previously described in connection with FIGS. 1A–6, and primed reference numerals are used for elements which are similar in construction, design, and operation, as those previously described in connection with FIGS. 1A–6.

As seen in FIG. 7, graft, or prosthesis, 70' generally includes a plurality of prostheses, or grafts 70 as described previously in connection with FIGS. 1A, 1B, and 2. Preferably, the length of each graft, or prosthesis, 70 is approximately the length of one slot 82; however, the length of each graft 70 could be approximately equal to the length of two slots 82, as illustrated in FIG. 1A. Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is at least one connector member 100 to flexibly connect adjacent tubular members 71, or grafts, or prostheses, 70. Connector member, or members, 100 are preferably formed of the same materials as grafts 70, as previously described, and connector members 100 may be formed integrally between adjacent grafts 70, or tubular members, 71 as shown in FIG. 7. As seen in FIG. 8, the cross-sectional configuration of connector member, or members, 100, along the longitudinal axis of graft, or prosthesis 70', is the same, in that connector member, or members, 100 have the same uniform wall thickness of elongate members 75. Of course, it should be readily apparent to one of ordinary skill in the art, that the thickness of connector members 100 could alternatively be smaller than that of elongate members 75; however, it is preferable that the outer circumferential surface 101 of connector members 100 lies in the same plane formed by the wall surface 74 of grafts, or prostheses 70, as seen in FIG. 8.

Still with reference to FIGS. 7–8, connector members 100 are preferably disposed in a non-parallel relationship with respect to the longitudinal axis of adjacent grafts, or prostheses, 70. Further, it is preferable that the at least one connector member 100 is formed as a thin-walled spiral member 102 which is coplanar with the outer wall surface 74 of the adjacent tubular members 71, or adjacent grafts, or prostheses, 70. It should be noted that although graft, or prosthesis, 70' is illustrated as including three grafts, or prostheses, 70 flexibly connected to one another by connector members 100, as few as two grafts 70 could be connected to form graft, or prosthesis, 70'. Furthermore, many grafts 70 could be flexibly connected by connector members 100 as are desired to form graft, or prosthesis, 70'.

The delivery and expansion of graft or prosthesis, 70' is the same as that previously described in connection with FIGS. 1A, 1B, and 3–4. The length of the expandable, inflatable portion 84 of catheter 83 would be sized to conform with the length of graft, or prosthesis, 70,, as should be readily apparent to one of ordinary skill in the art. Except for the length of the expandable, inflatable portion 84 of catheter 83, the method of delivery of graft, or prosthesis, 70' and its subsequent, controllable expansion and deformation is the same as previously described.

With reference to FIG. 9, the prosthesis 70' is illustrated in the configuration it would assume when being delivered to the desired location within the body passageway 80 and the graft, or prosthesis, 70' is disposed upon catheter 83 and is passing through a curved portion of body passageway 80, such as an arterial bend. For clarity, catheter 83 is not shown in FIG. 9, since the flexibility of such catheters 83 is well known in the art. As seen in FIG. 9, because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70' is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways 80. As seen in FIG. 9, as graft, or prosthesis, 70' bends, or articulates about the longitudinal axis of graft 70', the spacing between tubular members 71 increases, or expands, about the outer side of the curve, or bend, 103; and the spacing decreases, or is compressed, on the inner side of the curve, or bend, 104. Likewise, spiral connector members 102 adjacent the outer side of the curve 103 flexibly and resiliently stretch to permit the expansion of the spacing thereat; and the spiral connector members 102 adjacent the inner side of the curve, 104 flexibly and resiliently compress to permit the decrease in the spacing between tubular members 71 on the inner side of curve 104. It should be noted that connector members 100 permit the bending, or articulation, of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'.

Turning now to FIG. 10, graft, or prosthesis, 70' is illustrated in its expanded, and deformed configuration, similar to that illustrated in FIG. 1B. It should be noted that should it be desired to implant graft, or prosthesis, 70' on a curved portion of a body passageway 80, such

implantation and expansion would be permitted by the connector members 100. It should also be noted that prostheses, or grafts, 70 could be flexibly connected to one another to form a graft, or prosthesis, 70' wherein such grafts, or prostheses, 70 are formed as wire mesh tubes of the type illustrated in Applicant's co-pending application, Ser. No. 06/796,009, filed Nov. 7, 1985, entitled, "Expandable Intraluminal Graft, and Method and Apparatus for Implanting an Expandable Intraluminal Graft", which application is incorporated by reference herein.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials, or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

What is claimed is:

1. A method for implanting a plurality of prostheses within a body passageway comprising the steps of:

disposing at least one connector member between adjacent prostheses to flexibly connect adjacent prostheses to each other;

disposing the plurality of connected prostheses upon a catheter;

inserting the prostheses and catheter within the body passageway by catheterization of said body passageway; and

providing controllable expansion of at least one of the prostheses at a desired location within the body passageway by expanding a portion of the catheter associated with the prostheses to force at least one of the prostheses radially outwardly into contact with the body passageway, by deforming a portion of the at least one prosthesis with a force in excess of the elastic limit of the portion of the at least one prosthesis, to implant the prostheses within the body passageway.

2. The method of claim 1, further including the steps of: collapsing the portion of the catheter associated with the prostheses, and removing the catheter from the body passageway.

3. The method of claim 1, including the steps of: utilizing a catheter having an expandable, inflatable portion associated therewith; and the expansion and deformation of the prostheses and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

4. The method of claim 1, wherein at least one prosthesis is provided with a biologically compatible coating on the outer surface of the prosthesis.

5. The method of claim 1, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of adjacent prostheses.

6. The method of claim 1, including the step of: utilizing a wire mesh tube as each prosthesis, the wire mesh tubes having a first predetermined collapsed diameter which permits the tubes to be disposed upon the catheter and inserted into the body passageway.

7. The method of claim 6, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

8. The method of claim 6, wherein tantalum is utilized for the wire mesh tube.

9. The method of claim 1, wherein a thin-walled, tubular member is utilized as each prosthesis, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member.

10. The method of claim 9, wherein tantalum is utilized for the tubular member.

11. The method of claim 9, wherein the slots are uniformly and circumferentially spaced from adjacent slots and the slots are uniformly spaced from adjacent slots along the longitudinal axis of each tubular member, whereby at least one elongate member is formed between adjacent slots.

12. The method of claim 11, wherein the thin-walled tubular member and the elongate members disposed between adjacent slots have a uniform wall thickness.

13. The method of claim 9, wherein each thin-walled tubular member is expanded and deformed to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the internal diameter of the body passageway, whereby each expanded thin-walled tubular member will not migrate from the desired location within the body passageway and the expansion of each thin-walled tubular member does not cause a rupture of the body passageway.

14. The method of claim 13, wherein each thin-walled tubular member is uniformly, outwardly expanded and deformed along its length.

15. The method of claim 9, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

16. The method of claim 9, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

17. A method for expanding the lumen of a body passageway comprising the steps of:

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts;

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal rafts remain in the passageway.

18. The method of claim 17, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of the intraluminal grafts.

19. The method of claim 17, including the step of: utilizing a wire mesh tube as the intraluminal graft, the wire mesh tube having a first predetermined, collapsed diameter which permits the tube to be inserted within the body passageway at the desired location.

20. The method of claim 19, including the step of disposing the at least one connector member coplanar with each wire mesh tube and non-parallel to the longitudinal axis of the wire mesh tubes.

21. The method of claim 19, wherein tantalum is utilized for the wire mesh tube.

22. The method of claim 17, wherein a thin-walled tubular member is utilized as each intraluminal graft, each tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular members.

23. The method of claim 22, including the step of disposing the at least one connector member coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

24. The method of claim 22, including the step of forming the at least one connector member as a thin-walled spiral member, coplanar with adjacent tubular members.

25. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

26. The expandable intraluminal graft of claim 25, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

27. The expandable intraluminal graft of claim 25, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

28. The expandable intraluminal graft of claim 25, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

29. An expandable prosthesis for a body passageway, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

30. The expandable prosthesis of claim 29, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

31. The expandable prosthesis of claim 29, wherein the at least one connector member is disposed coplanar with each tubular member and non-parallel to the longitudinal axis of the tubular members.

32. The expandable prosthesis of claim 29, wherein the at least one connector member is a thin-walled, spiral member, coplanar with adjacent tubular members.

33. An apparatus for intraluminally reinforcing a body passageway, comprising:

a plurality of expandable and deformable, thin-walled tubular prostheses, each prosthesis having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the prostheses, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, thin-walled tubular prostheses on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the prostheses are expanded and deformed radially outwardly into contact with the body passageway.

34. The apparatus of claim 33, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable, tubular prostheses.

35. An apparatus for expanding the lumen of a body passageway comprising:

a plurality of expandable and deformable thin-walled intraluminal vascular grafts, each graft having first and second ends, and a wall surface disposed between the first and second ends, the wall surface having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axes of the grafts, at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members; and

a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable, deformable intraluminal vascular grafts on the expandable, inflatable portion,

whereby upon inflation of the expandable, inflatable portion of the catheter, the intraluminal vascular grafts are expanded and deformed radially outwardly into contact with the body passageway.

36. The apparatus of claim 35, wherein the mounting and retaining means comprises retainer ring members disposed on the catheter adjacent the expandable, inflatable portion and adjacent the ends of the expandable intraluminal vascular grafts.

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United States Patent [19]

Schatz

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[54] EXPANDABLE INTRALUMINAL GRAFT

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[58] Field of Search 600/36; 604/96, 104; 606/193, 194, 195; 623/1, 12

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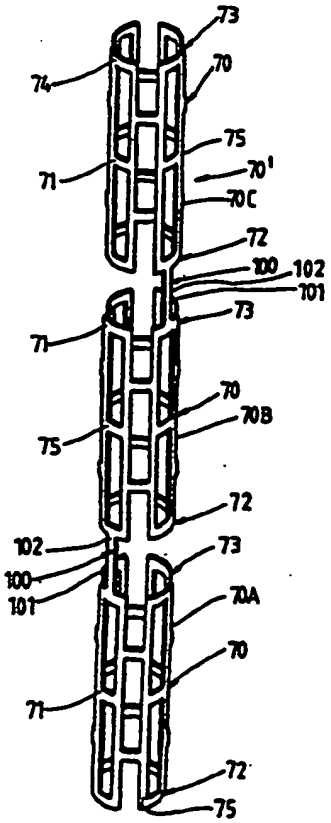
Primary Examiner—Paul Prebilic

Attorney, Agent, or Firm—Ben D. Tobor

[57] ABSTRACT

A plurality of expandable and deformable intraluminal vascular grafts are expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The grafts may be thin-walled tubular members having a plurality of slots disposed substantially parallel to the longitudinal axis of the tubular members, and adjacent grafts are flexibly connected by a single connector member disposed substantially parallel to the longitudinal axis of the tubular members.

6 Claims, 3 Drawing Sheets



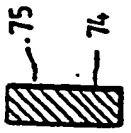


Fig. 2

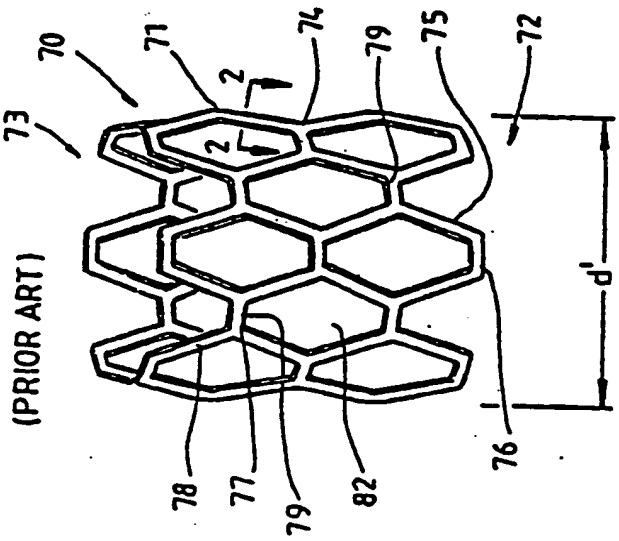


Fig. 1B
(PRIOR ART)

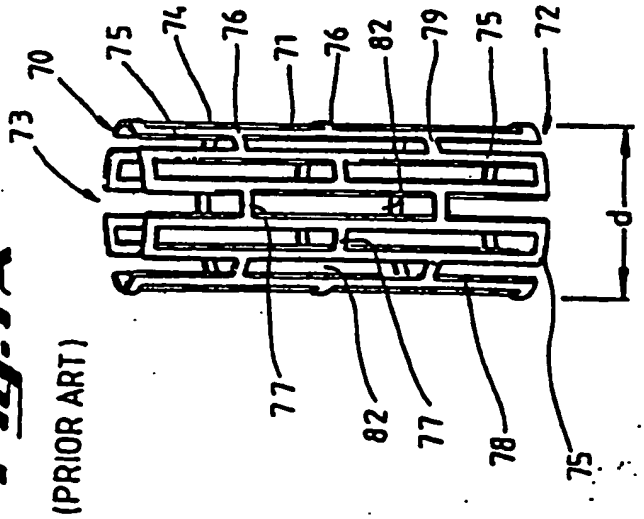
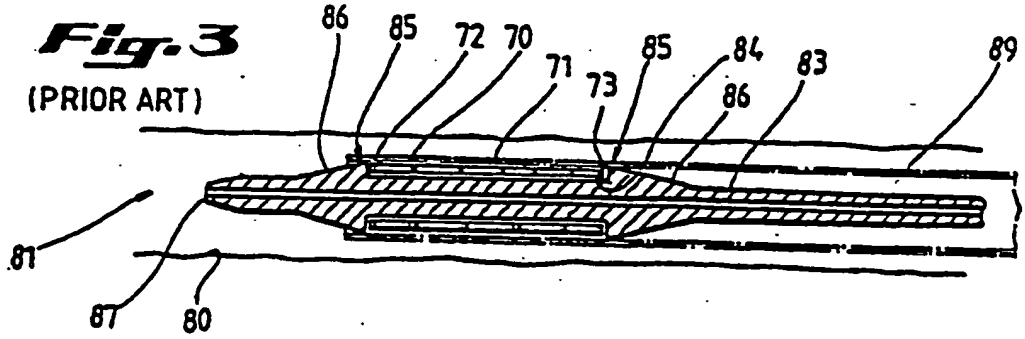


Fig. 1A
(PRIOR ART)

Fig. 3
(PRIOR ART)



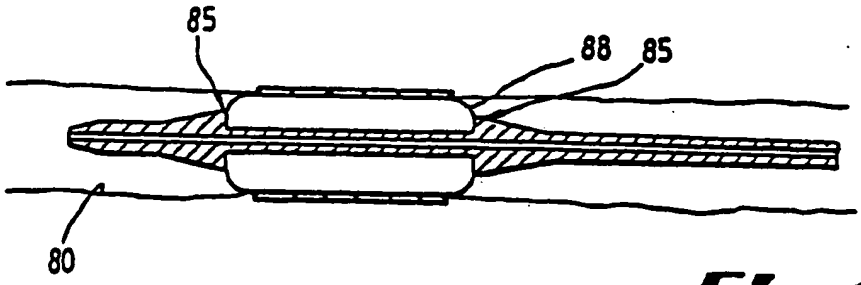
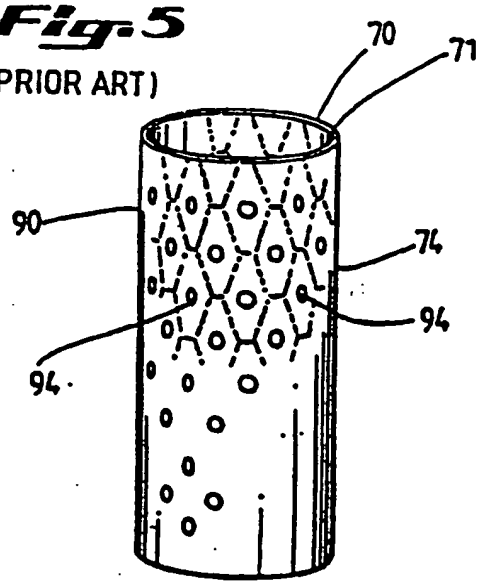


Fig. 4
(PRIOR ART)

Fig. 5
(PRIOR ART)



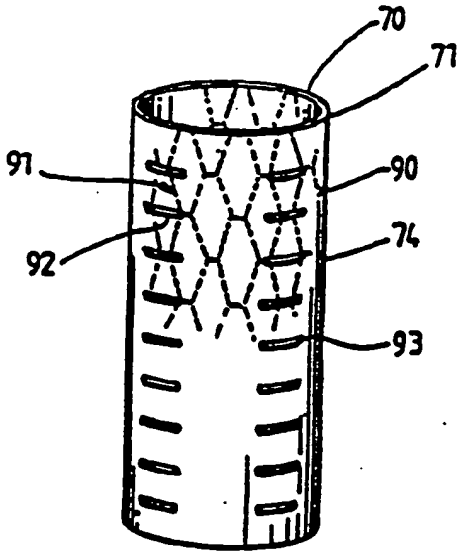


Fig. 6
(PRIOR ART)

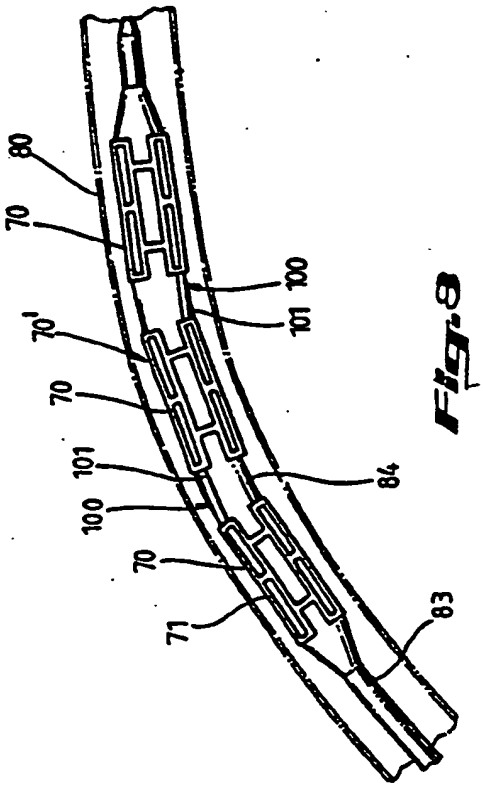
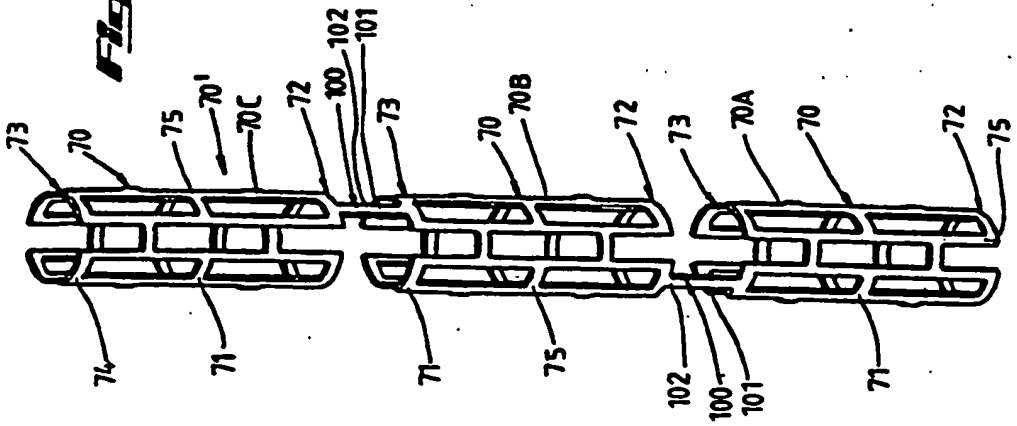

80
70
100
101
70'
70
101
100
70
71
84
83

Fig. 8

Fig. 7


73
70
75
70'
70C
72
100
102
101
73
70
70B
72
73
70A
70
72
75
74
71
71
75
102
100
101
71

EXPANDABLE INTRALUMINAL GRAFT

This application is a division of application Ser. No. 07/253,115, filed Oct. 4, 1988 now abandoned.

1. Field of the Invention

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

2. Description of the Prior Art

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material: and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway. Further, the constant outwardly radiating force exerted upon the interior surface of the body passageway can cause erosion of the internal surface, or intima, of the artery or body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter

mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postendarterectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

For repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the length of the body passageway which requires repair, as by the insertion of a tubular prosthetic graft, may present problems if the length of the required graft cannot negotiate the curves or bends of the body passageway

through which the graft is passed by the catheter. In other words, in many instances, it is necessary to support a length of tissue within a body passageway by a graft, wherein the length of the required graft exceeds the length of a graft which can be readily delivered via a catheter to the desired location within the vascular system. Some grafts do not have the requisite ability to bend so as to negotiate the curves and bends present within the vascular system, particularly prostheses or grafts which are relatively rigid and resist bending with respect to their longitudinal axes.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location and prevents rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system. Therefore, the art has sought an expandable intraluminal vascular graft which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location and to prevent rupturing and/or erosion of the body passageway by the expanded graft; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in the vascular system.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved by the present expandable intraluminal vascular graft. The present invention includes a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member; a single connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the single connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular members and coplanar with each tubular member; each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

A further feature of the present invention is that the single connector member may be a thin-walled, elongate bar member, coplanar with adjacent tubular members. An additional feature of the present invention is that a first connector member may be disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member may be disposed between the second end of the second tubular member and the first end of a third tubular member; the first and second connector members being angularly offset from one another with respect to the longitudinal axis of the tubular members.

The expandable intraluminal vascular graft of the present invention, when compared with previously proposed prior art intraluminal grafts, has the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; prevents erosion of the body passageway by the expanded graft; permits expansion of the graft to a variable size dependent upon conditions within the body passageway; permits tissue of an elongated section of a body passageway to be supported by an elongated graft; and provides the necessary flexibility to negotiate the bends and curves in tortuous body passageways, such as the vascular system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2 is a cross-sectional view of the prosthesis taken along line 2—2 of FIG. 1B;

FIG. 3 is a cross-sectional view of an apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, illustrating a prosthesis, or intraluminal vascular graft, in the configuration shown in FIG. 1A;

FIG. 4 is a cross-sectional view of the apparatus for intraluminally reinforcing a body passageway, or for expanding the lumen of a body passageway, with the graft, or prosthesis, in the configurations shown in FIG. 1B;

FIGS. 5 and 6 are perspective views of prostheses for a body passageway, with the grafts, or prostheses, having a coating thereon;

FIG. 7 is a perspective view of another embodiment of a graft or prosthesis in accordance with the present invention; and

FIG. 8 is a perspective view of the graft of FIG. 7, wherein the graft has been bent or articulated.

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. 1A and 1B, an expandable intraluminal vascular graft, or expandable prosthesis for a body passageway, 70 is illustrated. It should be understood that

the terms "expandable intraluminal vascular graft" and "expandable prosthesis" are interchangeably used to some extent in describing the present invention, insofar as the methods, apparatus, and structures of the present invention may be utilized not only in connection with an expandable intraluminal vascular graft for expanding partially occluded segments of a blood vessel, or body passageway, but may also be utilized for many other purposes as an expandable prosthesis for many other types of body passageways. For example, expandable prostheses 70 may also be used for such purposes as: (1) supportive graft placement within blocked arteries opened by transluminal recanalization, but which are likely to collapse in the absence of an internal support; (2) similar use following catheter passage through mediastinal and other veins occluded by inoperable cancers; (3) reinforcement of catheter created intrahepatic communications between portal and hepatic veins in patients suffering from portal hypertension; (4) supportive graft placement of narrowing of the esophagus, the intestine, the ureters, the urethra; and (5) supportive graft reinforcement of reopened and previously obstructed bile ducts. Accordingly, use of the term "prosthesis" encompasses the foregoing usages within various types of body passageways, and the use of the term "intraluminal vascular graft" encompasses use for expanding the lumen of a body passageway. Further, in this regard, the term "body passageway" encompasses any duct within the human body, such as those previously described, as well as any vein, artery, or blood vessel within the human vascular system.

Still with reference to FIGS. 1A and 1B, the expandable intraluminal vascular graft, or prosthesis, 70 is shown to generally comprise a tubular member 71 having first and second ends 72, 73 and a wall surface 74 disposed between the first and second ends 72, 73. Tubular member 71 has a first diameter, d, which, to be hereinafter described in greater detail, permits intraluminal delivery of the tubular member 71 into a body passageway 80 having a lumen 81 (FIG. 3). With reference to FIG. 1B, upon the application from the interior of the tubular member 71 of a radially, outwardly extending force, to be hereinafter described in greater detail tubular member 71 has a second, expanded diameter, d', which second diameter d, is variable in size and dependent upon the amount of force applied to deform the tubular member 71.

Tubular member 71, may be any suitable material which is compatible with the human body and the bodily fluids (not shown) with which the vascular graft, or prosthesis, 70 may come into contact. Tubular member 71 must also be made of a material which has the requisite strength and elasticity characteristics to permit the tubular member 71 to be expanded and deformed from the configuration shown in FIG. 1A to the configuration shown illustrated in FIG. 1B and further to permit the tubular member 71 to retain its expanded and deformed configuration with the enlarged diameter d' shown in FIG. 1B and resist radial collapse. Suitable materials for the fabrication of tubular member 71 would include silver, tantalum, stainless steel, gold, titanium or any suitable plastic material having the requisite characteristics previously described.

Preferably, tubular member 71 is initially a thin-walled stainless steel tube having a uniform wall thickness, and a plurality of slots 82 are formed in the wall surface 74 of tubular member 71. As seen in FIG. 1A when tubular member 71 has the first diameter d, the slots 82 are disposed substantially parallel to the longitudinal axis of the tubular member 71. As seen in FIG. 1A, the slots 82 are preferably uniformly and circumferentially spaced from adjacent slots 82, as by connecting members 77, which connecting members 77 preferably have a length equal to the width of slots 82, as seen in FIG. 1A. Slots 82 are further uniformly spaced from adjacent slots 82 along the longitudinal axis of the tubular member 71, which spacing is preferably equal to the width of connecting members 77. Thus, the formation of slots 82 results in at least one elongate member 75 being formed between adjacent slots 82, elongate member 75 extending between the first and second ends, 72, 73 of tubular member 71, as seen in FIG. 1A.

Still with reference to FIG. 1A, each slot will have first and second ends with a connecting member 77 disposed at the first and second ends of slots 82. Preferably, the first and second ends of each slot 82 are disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Thus, connecting members 77, which are disposed at the first and second ends of each slot 82, and between elongate members 75, will in turn be disposed intermediate the first and second ends of adjacent slots 82 along the longitudinal axis of the tubular member 71. Accordingly, slots 82 are preferably uniformly and circumferentially spaced from adjacent slots, and slots 82 adjacent to one another along the longitudinal axis of tubular member 71 are in a staggered relationship with one another. Alternating slots disposed about the circumference of tubular member 71 at both the first and second ends 72, 73 of tubular member 71 will only have a length equal to approximately one-half of the length of a complete slot 82, such half-slot 82 being bounded by members 78, 79, at both the first and second ends 72, 73 of tubular member 71. Although the graft, or prosthesis, 70 of FIGS. 1A and 1B is illustrated to have a length approximately equal to the length of two slots 82, it should be apparent that the length of the graft 70 could be made longer or shorter as desired.

The foregoing described construction of graft, or prosthesis, 70 permits graft, or prosthesis, 70 to be expanded uniformly, and outwardly, in a controlled manner into the configuration shown in FIG. 1B, upon the application of a suitable force from the interior of tubular member 71, as will be hereinafter described in greater detail. The expansion of tubular member 71 into the configuration shown in FIG. 1B is further uniform along the length of tubular member 71, not only because of the uniform spacing between slots 82, as previously described, but also because the thickness of the wall surface 74, or the thickness of connecting members 77, elongate members 75, and members 78, 79, is the same uniform thickness. As illustrated in FIG. 2, the uniform thickness of elongate member 75 is shown, and the preferred cross-sectional configuration of elongate member 75, connecting member 77, and members 78, 79, is illustrated, which configuration is rectangular. It should of course be understood by those skilled in the art, that the cross-sectional configuration of the foregoing components of graft, or prosthesis, 70 could also be square, rectangular, or other cross-sectional configurations. As will be hereinafter described in greater detail, it is preferable that the outer surface 74 of graft, or prothesis, 70, which would be in contact with the body passageway 80 FIG. 4, should be relatively smooth.

With reference to FIG. 1B, it is seen that after the graft, or prosthesis 70, has been expanded and deformed

into the configuration of FIG. IB, the slots 82 will assume a substantially hexagonal configuration when the tubular member 71 has the second, expanded diameter, d', as shown in FIG. 1B. Such a hexagonal configuration will result when the slots 82 initially have a substantially rectangular configuration when the tubular member 71 has the first diameter, d, illustrated in FIG. 1A. It should be noted that were the width of slots 82 to be substantially reduced, whereby the length of connecting member 77 would approximate a single point intersection, the expansion of such a tubular member 71 would result in slots 82 assuming a configuration which would be substantially a parallelogram (not shown).

It should be noted that not only is tubular member 71 expanded from the configuration shown in FIG. 1A to achieve the configuration shown in FIG. 1B, but tubular member 71 is further "deformed" to achieve that configuration. By use of the term "deformed" is meant that the material from which graft, or prosthesis, 70 is manufactured is subjected to a force which is greater than the elastic limit of the material utilized to make tubular member 71. Accordingly, the force is sufficient to permanently bend elongate members 75 whereby segments of the elongate members 75 pivot about connecting members 77 and move in a circumferential direction as they pivot, whereby the diameter of the tubular member 71 increases from the first diameter, d, to the expanded diameter, d', of FIG. 1B. The force to be applied to expand tubular member 71, which is applied in the manner which will be hereinafter described in greater detail, must thus be sufficient to not only expand tubular member 71, but also to deform elongate member 75, in the manner previously described, whereby the portions of the elongate members 75 which pivot about the ends of connecting members 77 do not "spring back" and assume their configuration shown in FIG. 1A, but rather retain the configuration thereof in FIG. 1B. Once graft, or prosthesis, 70 has been expanded and deformed into the configuration shown in FIG. 1B, graft, or prosthesis 70, will serve to prevent a body passageway from collapsing as will be hereinafter described in greater detail. It should be noted that when tubular member 71 has the first diameter, d, shown in FIG. 1A, or after tubular member 71 has been expanded and deformed into the second, expanded diameter, d', of FIG. 1B, tubular member 71 does not exert any outward, radial force, in that tubular member 71 is not a "spring-like" or "self-expanding member", which would tend to exert an outwardly radial force.

With reference now to FIGS. 3 and 4, apparatus of the present invention will be described in greater detail. Once again, it should be understood that the apparatus of the present invention is useful not only for expanding the lumen of a body passageway, such as an artery, vein, or blood vessel of the human vascular system, but are also useful to perform the previously described procedures to intraluminally reinforce other body passageways or ducts, as previously described. Still with reference to FIGS. 3 and 4, an expandable intraluminal vascular graft, or prosthesis, 70, of the type described in connection with FIGS. 1A and 1B, is disposed or mounted upon a catheter 83. Catheter 83 has an expandable, inflatable portion 84 associated therewith. Catheter 83 may include means for mounting and retaining 85 the expandable intraluminal vascular graft, of prosthesis, 70 on the expandable, inflatable portion 84 of catheter 83. The mounting and retaining means 85 could comprise retainer ring members 86 disposed on the catheter 83 adjacent the expandable inflatable portion 84 of catheter 83; and a retainer ring member 86 is disposed adjacent each end 72, 73 of the expandable intraluminal vascular graft, or prosthesis, 70. As seen in FIG. 3, retainer ring members could be formed integral with catheter 83, and the retainer ring member 86 adjacent the leading tip 87 of catheter 83 slopes upwardly and away from catheter tip 87 in order to protect and retain graft or prosthesis, 70 as it is inserted into the lumen 81 of body passageway 80, as to be hereinafter described in greater detail. The remaining retainer ring member 86 as shown in FIG. 3, slopes downwardly away from tip 87 of catheter 83, to insure easy removal of catheter 83 from body passageway 80. After expandable intraluminal graft, or prosthesis, 70 has been disposed upon catheter 83, in the manner previously described, the graft, or prosthesis, 70 and catheter 83 are inserted within a body passageway 80 by catheterization of the body passageway 80 in a conventional manner.

In a conventional manner, the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway 80, whereat it is desired to expand the lumen 81 of body passageway 80 via intraluminal graft 70, or where it is desired to implant prosthesis 70. Fluoroscopy, and/or other conventional techniques may be utilized to insure that the catheter 83 and graft, or prosthesis, 70 are delivered to the desired location within the body passageway. Prosthesis, or graft, 70 is then controllably expanded and deformed by controllably expanding the expandable, inflatable portion 84 of catheter 83, whereby the prosthesis, or graft, 70 is expanded and deformed radially, outwardly into contact with the body passageway 80, as shown in FIG. 4. In this regard, the expandable, inflatable portion of catheter 83 may be a conventional angioplasty balloon 88. After the desired expansion and deformation of prosthesis, or graft, 70 has been accomplished, angioplasty balloon 88 may be collapsed, or deflated, and the catheter 83 may be removed in a conventional manner from body passageway 80. If desired, as seen in FIG. 3, catheter 83, having graft or prosthesis, 70 disposed thereon, may be initially encased in a conventional Teflon sheath 89, or a sheath 89 made of another suitable material, which is pulled away from prosthesis, or graft, 70, prior to expansion of the the prosthesis, or graft, 70.

Still with reference to FIGS. 3 and 4, it should be noted that tubular member 71 of prosthesis, or graft, 70 initially has the first predetermined, collapsed diameter, d, as described in connection with FIG. 1A, in order to permit the insertion of the tubular member, 71 into the body passageway 80 as previously described. When it is desired to implant prosthesis 70 within a body passageway 80 for the purposes previously described, the prosthesis 70 is, controllably expanded and deformed to the second diameter, d', and the second, expanded diameter, d_n, is variable and determined by the internal diameter of the body passageway 80, as shown in FIG. 4, and by the amount of expansion of the inflatable portion 84 of catheter 83. Accordingly, the expanded and deformed prosthesis 70, upon deflation of angioplasty balloon 88 will not be able to migrate from the desired location within the body passageway 80, nor will the expansion of the prosthesis 70 be likely to cause a rupture of the body passageway 80. Furthermore, insofar as prosthesis, or graft, 70 is not a "spring-like" or "self-expanding member", the prosthesis is not consistently applying an outward, radial force against the interior surface of body passageway 80, in excess of that re-

quired to resist radial collapse of the body passageway 80. Thus, erosion of the interior surface, or intima, of the artery or body passageway is prevented.

When it is desired to use expandable intraluminal graft 70 to expand the lumen 81 of a body passageway 80 having an area of stenosis, the expansion of intraluminal vascular graft 70 by angioplasty balloon 88, allows controlled dilation of the stenotic area and, at the same time controlled expansion and deformation of the vascular graft 70, whereby vascular graft 70 prevents the body passageway 80 from collapsing and decreasing the size of the previously expanded lumen 81. Once again, the second, expanded diameter d' of intraluminal vascular graft 70, as shown in FIG. 4, is variable and determined by the desired expanded internal diameter of body passageway 80. Thus, the expandable intraluminal graft 70 will not migrate away from the desired location within the body passageway 80 upon deflation of angioplasty balloon 88, nor will the expansion of intraluminal graft 70 likely cause a rupture of body passageway 80, nor any erosion as previously described. Further, should an intimal flap, or fissure, be formed in body passageway 80 at the location of graft 70, graft 70 will insure that such an intimal flap will not be able to fold inwardly into body passageway 80, nor tear loose and flow through body passageway 80. In the situation of utilizing graft 70 in the manner previously described to expand the lumen of a portion of a critical body passageway, such as the left main coronary artery, it is believed that the intimal flap will be unable to occlude the left main coronary artery of the heart and cause the death of the patient.

Because it is only necessary to inflate angioplasty balloon 88 one time in order to expand and deform graft 70, it is believed that a greater amount of endothelium, or inner layer of the intima, or inner surface of the body passageway, will be preserved, insofar as the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time. Further, in theory, the amount of preserved endothelium should be large because in the expanded configuration of graft 70, potentially 80% of the endothelium is exposed through the openings or expanded slots 82 of graft 70. It is further believed that intact patches of endothelium within expanded slots 82 of graft 70 may result in a rapid, multicentric endothelialization pattern as shown by experimental studies.

With reference now to FIGS. 5 and 6, prostheses, or grafts, 70 of the type previously described in connection with FIGS. 1A and 1B are shown, and the tubular members 71 of grafts, or prostheses, 70 have a biologically inert or biologically compatible coating 90 placed upon wall surfaces 74 of tubular shaped members 71. Examples of a suitable biologically inert coating would be porous polyurethane, Teflon—, or other conventional biologically inert plastic materials. The coating 90 should be thin and highly elastic so as not to interfere with the desired expansion and deformation of prosthesis, or graft, 70. Coating 90 may be further provided with a means for anchoring 91 (FIG. 6) the tubular member 71 to the body passageway 80. Anchoring means 91 may be comprised of a plurality of radially, outwardly extending projections 92 formed on the coating 90. As seen in FIG. 6, the radially outwardly extending projections 92 could comprise a plurality of ridges 93, or other types of radially, outwardly extending projections. Further, it may be desirable to have a plurality of openings 94 formed in coating 90, as shown in FIG. 5, whereby the fluid contained in body passageway 80 can be in direct contact with the dilated, or expanded, body passageway area. Examples of biologically compatible coatings 90 would include coatings made of absorbable polymers such as those used to manufacture absorbable sutures. Such absorbable polymers include polyglycoides, polylactides, and copolymers thereof. Such absorbable polymers could also contain various types of drugs, whereby as the coating 90 is absorbed, or dissolves, the drug would be slowly released into the body passageway 80.

Turning now to FIGS. 7 and 8, an expandable intraluminal vascular graft, or prosthesis, 70' is shown for implantation in curved body passageways 80, or for use in the elongated sections of body passageway 80, when a prosthesis or a graft, 70' is required which is longer than the graft, or prosthesis, 70 of FIG. 1A. Identical reference numerals are used throughout FIGS. 7 and 8 for elements which are the same in design, construction, and operation, as those previously described in connection with FIGS. 1A–6, and primed reference numerals are used for elements which are similar in construction, design, and operation, as those previously described in connection with 1A–6.

As seen in FIG. 7, graft, or prosthesis, 70' generally includes a plurality of prostheses, or grafts, 70 as described previously in connection with FIGS. 1A, 1B, and 2. Disposed between adjacent tubular members, 71, or adjacent grafts, or prostheses, 70, is a single connector member 100 to flexibly connect adjacent tubular members 71 or grafts, or prostheses, 70. Connector members 100 are preferably formed of the same material as grafts 70, as previously described, and connector members 100 may be formed integrally between adjacent grafts 70, or tubular members 71, as shown in FIG. 7. The cross-sectional configuration of connector members 100, along the longitudinal axis of graft, or prosthesis, 70', is the same, in that connector members 100 have the same uniform wall thickness of elongate members 75 and thus form a thin-walled, elongate bar member 101 which is coplanar with adjacent tubular members 71. Of course, it should be readily apparent to one of ordinary skill in the art, that the thickness of connector members 100 could alternatively be smaller than elongate member 75; however, it is pre ferable that the outer circumferential surface 102 of connector members 100 lies in the same plane formed by the wall surfaces 74 of grafts, or prostheses, 70, as seen in FIG. 7.

Still with reference to FIGS. 7–8, it should be noted that although graft, or prosthesis, 70' is illustrated as including three grafts, or prostheses, 70 flexibly connected to one another by connector members 100, as few as two grafts 70 could be connected to form graft, or prosthesis, 70'. Furthermore, many grafts 70 could be flexibly connected by connector members 100 as are desired to form graft, or prosthesis, 70'. Preferably, the length of each graft, or prosthesis, 70 is approximately the length of two slots 82; however, the length of each graft 70 could be approximately equal to the length of two or more slots 82. When three or more grafts 70 are flexibly connected by connector members 100, as shown in FIGS. 7 and 8, preferably a first connector member 100 is disposed between the second end 73 of a first tubular member 70A and the first end 72 of a second tubular member 70B. A second connector member 100 is then disposed between the second end 73 of the second tubular member 70B and the first end 72 of a third tubular member 70C. The first and second connec-

tor members 100, as shown in FIGS. 7 and 8, may be angularly offset from one another with respect to the longitudinal axis of the tubular members 70 to permit the requisite flexibility between the interconnected grafts, or prostheses, 70.

The delivery and expansion of graft, or prosthesis, 70' is the same as that previously described in connection with FIGS. 1A, 1B, and 3–4. The length of the expandable, inflatable portion 84 of catheter 83 would be sized to conform with the length of the graft, or prosthesis, 70', as should be readily apparent to one of ordinary skill in the art. Except for the length of the expandable, inflatable portion 84, catheter 83, the method of delivery of graft, or prosthesis, 70' and its subsequent, controllable expansion and deformation are the same as previously described. As seen in FIG. 8, the prosthesis 70' is illustrated in the configuration it would assume when being delivered to the desired location within the body passageway 80, and the graft, or prosthesis, 70' is disposed upon catheter 83 and is passing through a curved portion of body passageway 80, such as an arterial bend. Because of the disposition of flexible connector members 100 between adjacent tubular members 71, or grafts, or prostheses, 70, graft, or prosthesis, 70' is able to flexibly bend, or articulate, with respect to the longitudinal axis of graft, or prosthesis, 70', so as to be able to negotiate the curves or bends found in body passageways 80. It should be noted that connector members 100 permit the bending, or articulation of adjacent tubular members 71 in any direction about the longitudinal axis of graft, or prosthesis, 70'. When graft, or prosthesis, 70' is in its expanded, and deformed configuration, tubular members 71 of graft, or prosthesis, 70', will assume the configuration shown in FIG. 1B.

It is to be understood that the invention is not to be limited to the exact details of construction, operation, exact materials, or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. Accordingly, the invention is therefore to be limited only by the scope of the appended claims.

I claim:

1. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

only one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular members and coplanar with each tubular member.

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

2. The expandable intraluminal graft of claim 1, wherein the connector member is a thin-walled, elongate bar member, coplanar with adjacent tubular members.

3. The expandable intraluminal graft of claim 1, wherein a first connector member is disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member is disposed between the second end of the second tubular member and the first end of a third tubular member, the first and second connector members being angularly offset from one another and with respect to the longitudinal axes of the tubular members they interconnect.

4. An expandable prosthesis for a body passageway, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

only one single connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members, the connector member being disposed in a substantially parallel relationship with respect to the longitudinal axis of the tubular members and coplanar with each tubular member;

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members, of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

5. The expandable prosthesis of claim 4, wherein the connector member is a thin-walled, elongate bar member, coplanar with adjacent tubular members.

6. The expandable prosthesis of claim 4, wherein a first connector member is disposed between the second end of a first tubular member and the first end of a second tubular member; a second connector member is disposed between the second end of the second tubular member and the first end of a third tubular member, the first and second connector members being angularly offset from one another and with respect to the longitudinal axes of the tubular members they interconnect.

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Self-Expanding Endovascular Graft: An Experimental Study in Dogs

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An arterial endovascular graft was constructed by wrapping an expandable nylon mesh around a framework of Gianturco self-expanding metallic stents. The devices were passed through a 12-French Teflon catheter and positioned in the normal abdominal aorta of five dogs, two of which also had a device placed in an external iliac artery. At follow-up (1–6 months), all grafts remained patent, even though slight luminal narrowing due to neointimal encasement was noted. Histologically, all grafts were covered by neointimal proliferation at the time of removal. The graft material expanded with the stents, resulting in a tight fit between the graft and the vessel wall. Side branches narrowed but remained open because of the size of the nylon mesh. No migration of the grafts equipped with a barbed lead stent was noted.

Expandable nylon mesh can be used as an endovascular graft material when wrapped around a framework of self-expanding stents. The resulting device can be easily delivered via transcatheter techniques, and once placed in a vessel, the nylon acts as a support for neointimal encasement, which forms a new vascular lumen.

Since Dotter first described coiled stainless steel wire stents in 1969 [1], many types of endovascular stents and grafts have been developed [2–9]. In recent years, several reports have been published on the experimental and clinical applications of the self-expanding Gianturco stent [5, 8, 10–16]. Clinically, these stents have been found to effectively dilate stenoses and prevent recurrence in the vena cava [13], the tracheobronchial tree [12], and the biliary tract (Irving D, unpublished data).

We describe a new arterial endovascular graft constructed by wrapping an expandable nylon mesh (light-support panty hose) around the Gianturco stents. Preliminary results obtained in the normal aorta of five dogs and in the normal external iliac arteries of two of these dogs are reported.

Materials and Methods

The endovascular graft consisted of two parts: (1) a framework composed of three or four self-expanding stents and (2) an expandable nylon (88% nylon and 12% lycra spandex) cylinder (Fig. 1). The stents were constructed of 0.016-in. (0.4 mm) stainless-steel wire bent in a zigzag configuration containing six bends at each end. The stents were constructed in two sizes: (1) 2.5 cm in length and 2.3 cm in fully expanded diameter for the abdominal aorta and (2) 1.8 cm in length and 1.2 cm in fully expanded diameter for the external iliac artery. Three or four stents were connected in tandem by metallic struts constructed from the same wire. The first stent was the lead stent, which acted as an anchor for the graft. This stent was equipped with barbs when placed in the aorta only, and in all cases, it was not covered by the nylon. The material covered the other stents and was forced open when the device was released from the introducing catheter.

The nylon cylinders were constructed in two sizes: (1) 1.0 cm in diameter and 4.0 cm (three stents) or 6.0 cm (four stents) in length for the abdominal aorta and (2) 0.7 cm in diameter and 3.0 cm in length for the external iliac artery. The nylon mesh was wrapped around the outside of all but the lead stent. The ends of the graft were attached to the framework with

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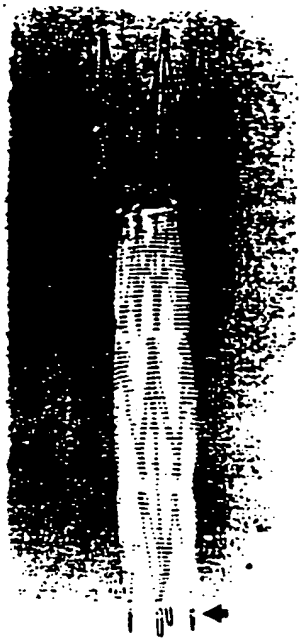

Fig. 1.—Photograph of an endovascular stent graft. Device consists of an expandable nylon cylinder supported by a framework of self-expanding stents. Note that ends of nylon cylinder are attached to superstructure with suture material passed through eyelets formed at wire bends (*arrows*).

6-0 monofilament suture material passed through eyelets formed by placing a bead of silver solder across the bends of the stent (Fig. 1).

The completed devices placed in the aorta were either 8 cm (three stents) or 11 cm (four stents) in length and 1.2 cm in fully expanded diameter. Those placed in the iliac artery were 6.0 cm (three stents) in length and 0.9 cm in fully expanded diameter. Complete expansion of the stents was limited by the nylon mesh.

Five adult mongrel dogs (22–28 kg) were used in this study. After each dog was given a general anesthetic (sodium pentobarbital, 30 mg/kg), a 12-French Teflon catheter was inserted through a femoral arteriotomy. After systemic heparin (100 U/kg) was given, the catheter was advanced under fluoroscopic monitoring into the area of interest. The grafts, which were sterilized with ethylene oxide, were then passed through the 12-French Teflon catheter into the normal infrarenal abdominal aorta of five dogs and into the normal external iliac arteries of two of the dogs by using the technique described previously [5].

Angiography was performed before and immediately after stent placement to evaluate vascular anatomy and stent position. After placement, angiograms were obtained at monthly intervals and at the end of the follow-up period. No anticoagulants or antiplatelet agents were administered after graft placement; heparin was given during follow-up angiographic studies.

The dogs were sacrificed by exsanguination under deep sodium-pentobarbital anesthesia after a follow-up of 1 month (one dog), 4 months (two dogs), 5 months (one dog), and 6 months (one dog). A complete necropsy was then performed, and the vessels containing the grafts were removed. In addition, if any portion of the device bridged a renal artery, the vessel and accompanying kidney were collected. All specimens were examined grossly and microscopically.

Results

No difficulties were encountered in the placement of the nylon stent grafts. Patency was maintained in all five aortic and in two iliac devices during the follow-up period. Stent grafts placed in the aorta did not migrate. One graft was too long and caused stenosis at the origin of the common internal iliac artery (Fig. 2). A graft in the right external iliac artery of one dog moved 5 mm cranially during the first month after placement, and the common internal iliac artery narrowed somewhat at its origin (Fig. 3). This graft did not have barbs on the lead stent.

Over the follow-up period of 1–6 months, diffuse luminal narrowing (<2 mm) was noted angiographically over the entire length of the nylon material only; no luminal narrowing was noted in the region of the lead stent (Figs. 2B and 3B). Blood vessels bridged by the lead stent remained patent and showed no indication of narrowing. Gradual narrowing of aortic side branches was observed at their origin where the nylon mesh was present. No extravasation or vascular perforation was noted in any of the dogs.

On postmortem examination, a thin, translucent covering was observed over the entire device (Fig. 4A). The nylon graft material conformed to the vessel wall, except in the proximal and the distal regions where the covering was thicker owing to a slight, longitudinal rippling of the material. This created small spaces between the nylon graft and the native vessel wall that were filled with proliferative tissue similar to that inside the lumen of the graft (Fig. 4B). This resulted in a slight reduction of the luminal diameter. No pleating was noted in the iliac grafts, but the cellular proliferation was thicker than

Fig. 2.—Abdominal aortograms of a dog with a stent graft in aorta.
A, Aortogram obtained immediately after placement shows device extending into external iliac bifurcation.
B, Aortogram obtained 6 months later shows stenosis has occurred at origin of iliac arteries bridged by device. However, all side branches covered by graft material have remained patent.

Fig. 3.—Abdominal aortograms of a dog with stent grafts in aorta and right external iliac artery.

A, Aortogram obtained immediately after placement.

B, Follow-up aortogram obtained 4 months later shows that device in external iliac artery has migrated approximately 5 mm cranially and that common internal iliac has narrowed somewhat at its origin (*arrow*). Again, all side branches bridged by graft material have remained open.

that in the aortic grafts. Neointimal encasement was not found on the wires of the lead stent that bridged side branches, whereas a cellular covering occurred at the origin of branches crossed by the graft material.

Renal arteries bridged by the lead stent showed no evidence of erosion, and no gross changes were seen in the kidneys supplied by the bridged arteries.

Histologically, intimal proliferation completely covered the graft and stent wires, and a single layer of endothelium lined the luminal surface. The intimal proliferation occurred both outside and inside the lumen of the nylon mesh. Side branches bridged by the graft material were narrowed at the origin by this cellular proliferation, but they were never occluded. No inflammatory changes were found in either the vessel wall or the associated lymph nodes. Small hemosiderin deposits were found occasionally in the native intima compressed by stent wires. Slight rippling of the nylon mesh was noted occasionally in areas where the graft diameter was too large for the recipient vessel (Fig. 4B).

Discussion

The nylon material used in the construction of the endovascular stent graft described in this report exhibited two important characteristics: (1) elasticity and (2) loose-weave mesh. Because the nylon was elastic, a cylinder could be constructed that was slightly smaller than the diameter of the recipient vessel. In this way, when the stent framework was allowed to expand, the material was stretched, thus creating a tight fit between the graft and the vessel wall. This prevented pleating of the material, created a single lumen through the area of interest, and reduced narrowing caused by the neointima covering the graft. Occasional rippling was noted in the aortic nylon grafts, but it was significantly less severe than that reported by Lawrence et al. [15], and could possibly have been prevented by making the graft cylinders smaller. In addition, the weave of the nylon material used in this study was relatively loose (Fig. 1). Because of this, blood was able to flow through the mesh into the side branches bridged by the material. In this way, blood flow in these arteries was compromised over a long period, allowing ample time for the formation of collateral vessels. Neointima was found on the nylon strands bridging the side branches, similar to that seen on the wires of the stents used by Sigwart et al. [9].

One disadvantage of the stent graft was that it required a 12-French catheter for introduction. This was a result of stent construction (wire size and number of bends at each end) as well as the elasticity and thickness of the nylon material. Stents were constructed of 0.016-in. (0.4-mm) wire and contained six bends at each end in order to obtain an expansile force great enough to expand the nylon mesh. Because the nylon was elastic, it had the tendency to bunch up at the distal end during insertion into the catheter.

One of the seven grafts placed in this project migrated. In this case, the lead stent was not equipped with barbs that

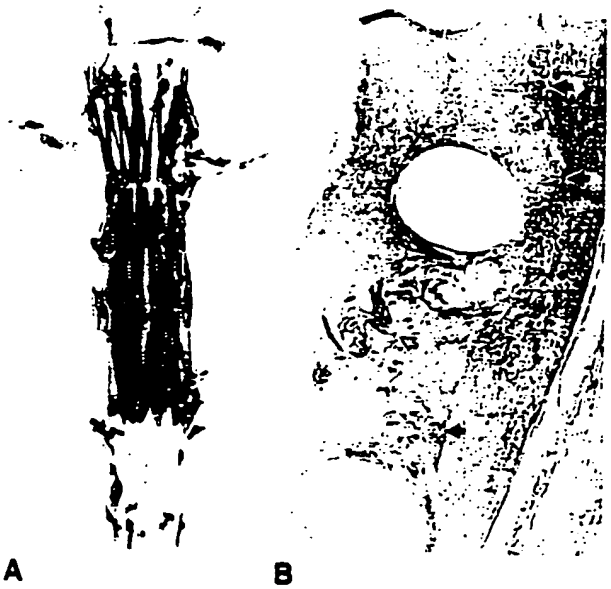

Fig. 4.—*A*, Photograph of an aortic stent graft removed 1 month after placement shows that entire device has been encased by a thin, translucent covering. This photograph was made after aorta was opened longitudinally and device was bisected.

B, Photomicrograph of a cross section made through an encased stent graft removed 6 months after placement shows nylon material (*solid arrows*) covered by neointima. Large discrete spaces are where stent wire was located. Note slight ripple in material (*open arrow*) that has been encased by neointima, resulting in a slight luminal bulge. (H and E, ×100)

engage the vessel wall and prevent movement during neointimal encasement. None of the stent grafts that were equipped with barbs migrated. This is similar to results reported by Chamsangavej et al. [13] and again emphasizes the need for barbs on the anchoring stent.

Cellular encasement was thicker in the external iliac grafts than in the aortic grafts, possibly because of the slower blood flow resulting from peripheral ligation of the ipsilateral femoral artery after placement of the devices. In addition, the expansile pressure of the stent against the iliac wall may have been greater than that in the aorta, which may have contributed to the excessive neointimal proliferation [14]. This indicates that stent grafts should be constructed of smaller wire when used in the more peripheral vessels.

In conclusion, the graft material supported by the stents acts as a framework for neointimal encasement that forms a new vascular lumen within the area of interest. In addition, anchoring stents should be equipped with barbs to help prevent migration, and the graft should be constructed of expandable, loose-weave material. Currently, saccular aortic aneurysms are being created experimentally to further evaluate these devices.

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Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents[1]

To test the ability of Gianturco expandable metallic stents to dilate and maintain patency in stenotic venae cavae, stenosis of the inferior vena cava was created in seven mongrel dogs by the percutaneous injection of absolute ethanol into the paravascular retroperitoneal space. Gianturco stents, placed across the stenotic segment, resulted in successful dilatation with improved hemodynamics in four dogs. The stents failed to dilate an occluded vena cava in one dog; in the remaining dogs, stent placement was complicated by early migration and occlusion. Gianturco stents were placed in two patients, one with superior vena cava syndrome and one with retroperitoneal fibrosis that obstructed the inferior vena cava, and resulted in immediate relief of presenting symptoms. These results should be viewed cautiously, but further investigation into the clinical use of the stents is indicated, especially for patients for whom other treatments are difficult.

Index terms: [illegible] • Vena cava, stenosis, 569.36

Radiology 1986; 161:295–298

In recent years, several types of vascular endoprostheses have been developed for vascular uses. Cragg et al (11) and Dotter et al (12) used a metallic alloy (nitinol) to form coil grafts. Palmaz et al (13) developed a balloon-assisted expandable graft with a thin stainless steel wire mesh in the wall, and Wright et al (14) evaluated the expandable metallic stent designed by Gianturco.

The Gianturco expandable metallic stent is constructed of a stainless steel wire bent in a zigzag pattern to form a cylinder. The stent can be compressed and introduced through a Teflon catheter of 8–12 Fr, depending on the caliber of the wire and the diameter of the stent. As the stent is released from the catheter, it expands to its original diameter. The expansile force varies with the caliber of the wire, the diameter and length of the stent, and the number and angle of the bends.

Wright et al (14), who studied use of the stent in the normal canine vena cava, found that proliferation of the endothelium covered the entire stent after placement. The caval lumen and orifices of caval side branches remained patent during two to three months of follow-up.

We report our evaluation of the ability of the Gianturco stent to dilate and maintain the patency of experimentally induced stenoses in the vena cava in dogs. We also describe clinical application of the stent in two patients with stenosis of the vena cava caused by tumor encasement or postsurgical and radiation fibrosis.

ANIMAL EXPERIMENT

Materials and Methods

Seven normal mongrel dogs, each weighing 20–25.5 kg, were used. Anesthesia was induced and maintained with sodium pentobarbital (30 mg/kg).

The stenotic vena cava was created by percutaneous injection of 20–30 mL of absolute ethanol through a 22-gauge needle into the retroperitoneal space around the inferior vena cava below the renal veins. Cavography of the inferior vena cava was used to guide the injection and was performed via the femoral or jugular vein approach. We attempted to place the needle tip in the caval wall or the paravascular space rather than in the lumen but the ethanol was injected.

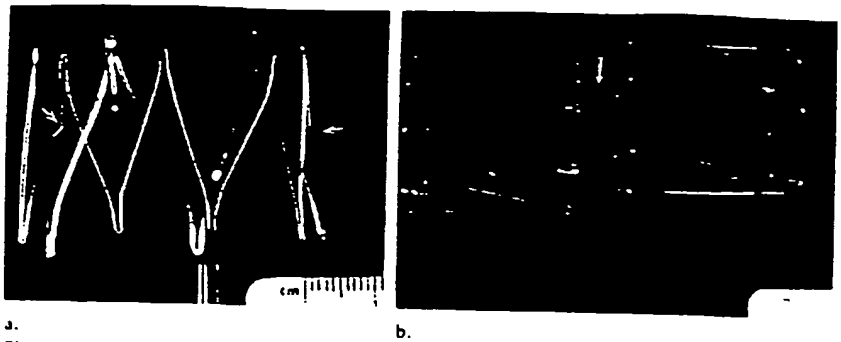
A significant stenosis was defined as a 50% decrease in the caval diameter or a pressure gradient across the stenosis of more than two times normal or 5 cm of saline, whichever was greater. In five of the seven dogs, a significant stenosis developed 2 weeks after the injection. In one dog, stenosis occurred at 1 week, but by 2 weeks the vena cava was occluded. In the remaining animal, a second injection of ethanol was necessary to achieve caval stenosis in 4 weeks.

After a significant stenosis developed, stents were placed across the narrowed segment. Three types of Gianturco stents were used. In the initial four dogs, a single stent or multiple stents of 0.035-cm (0.014-inch) wire, 2 cm in diameter and 3 cm long were used. To prevent migration, the stent was modified by attaching barbs (Fig 1a), which allowed the stent to become affixed to the wall of the vessel as it was released from the catheter. For a long stenosis, two stents of similar length were connected by wire struts (Fig 1b). They provided a greater expansile force than a single long stent and better stabilization. Migration was minimized by releasing the leading stent while the other stent remained in the catheter.

After a 10-F Teflon catheter was positioned at the desired location in the inferior vena cava, the stent was compressed and placed into the barrel end. The stent was advanced to the catheter tip with a pusher cable or catheter. To release the stent, the pusher cable was held stable and the catheter was withdrawn slowly until the stent was completely released and expanded. When multiple stents were placed, an attempt was made to bridge or overlap the adjoining stents. A similar catheter was used to place the barbed stent.

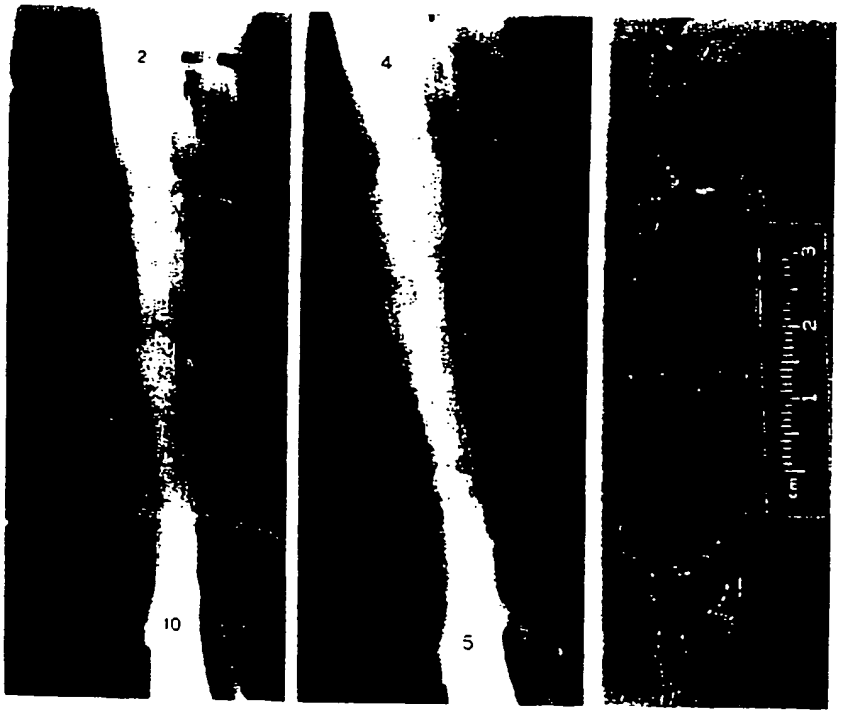
Conventional radiographs of the dogs

From the Department of Diagnostic Radiology, University of Texas M.D. Anderson Hospital and Tumor Institute, 6723 Bertner Ave., Houston, TX 77030. [illegible] from the 1985 RSNA annual meeting. Received March 19, 1986; accepted and revision requested May 7; revision received June 23. Address reprint requests to C.C.



a. b.

Figure 1. (a) Gianturco stent with barbs (arrows). (b) Double stent. Two stents connected by a wire strut (arrow) allow a greater expansile force than a single long stent and provide better stabilization during release



a. b. c.

Figure 2. Application of stents in experimentally induced caval stenosis in a dog. (Numbers in a and b represent pressure in centimeters of saline.) (a) Stenotic inferior vena cava after injection of absolute ethanol in the retroperitoneum. Pressure gradient across the stenosis was 8 cm of saline. (b) After placement of two single stents, pressure gradient was reduced to 1 cm of saline. (c) Pathologic specimen obtained 4 months after stent placement. The stents were covered by endothelium, incorporating them in the wall of the vessel.

Table 1
Effect of Stents on Inferior Vena Cava Diameter (mm)

Dog	Initial	Stenotic	After Stent Placement: Immediate	After Stent Placement: 4 Months Follow-up
1	15	5	7	9
		7	11	14
2	14	5	8	11
		9	14	14
3	14	5	9	12
4	16	4	7	9
		5	7	9

Note.—Caval diameters were measured at the different stenotic sites in dogs 1, 2, and 4.

a. b.

Figure 3. Failure of the stents. (a) Early migration resulted in a conical stent (arrows). (b) The closed end obstructed blood flow and thrombosis developed.

abdomens were obtained at 1, 2, 7, and 14 days after stent placement. Inferior cavography and pressure measurements above and below the stenosis were performed at monthly intervals for 4 months. No anticoagulants or antiplatelet agents were given to the dogs during the follow-up period. The dogs were killed when the stents failed or 4 months after placement. Pathologic examination of the retroperitoneum and inferior vena cava was performed.

Results

The stents were successfully placed across the stenosis, and the patency of the experimentally induced stenotic inferior vena cava was maintained in four of the seven dogs. There was an immediate increase in the caval diameter, varying from 2 to 5 mm after stent placement (Table 1). Although the inferior vena cava did not expand to its original diameter or to that of a fully expanded stent, it did expand up to another 3 mm in diameter from the time of placement to the time of sacrifice (Fig. 2). None of the stents migrated.

There was resolution of the pressure gradients in three of the four dogs; one did not have a significant pressure gradient before stent placement. Normal pressure gradients were maintained throughout the 4-month follow-up in all four dogs (Table 2).

Pathologic examination of the inferior vena cava in these four dogs demonstrated the stents to be incorporated in the caval wall (Fig. 2). Endothelial proliferation completely covered the stents in all. There was no clot formation. The orifices

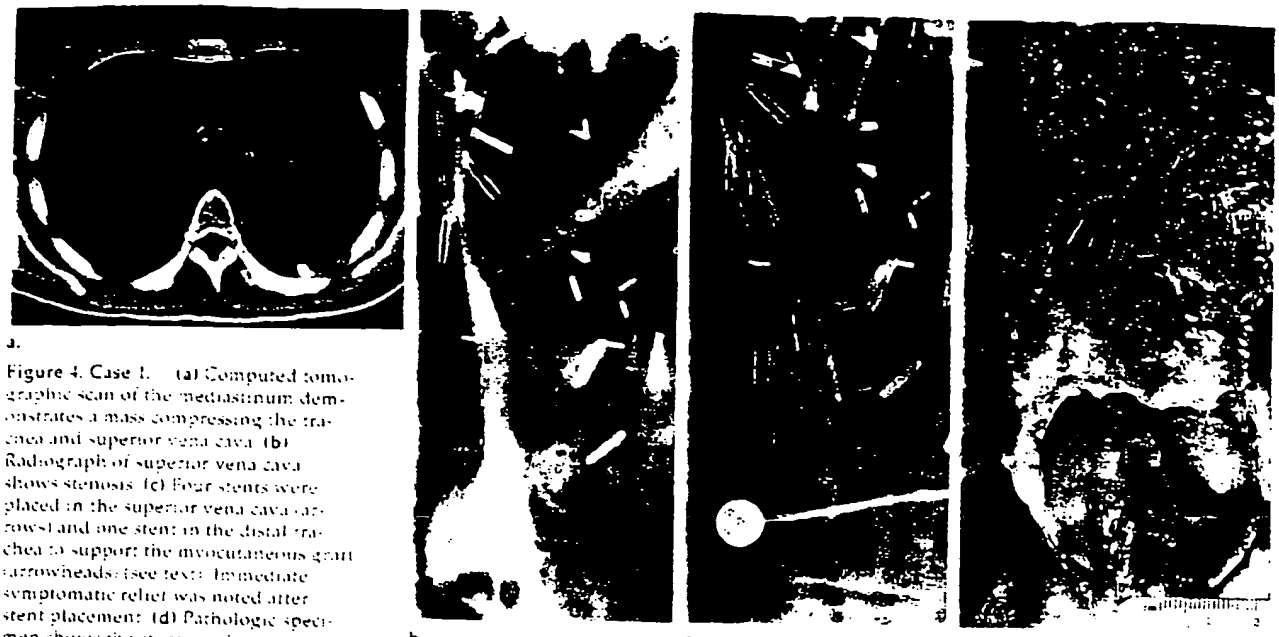


Figure 4. Case 1. (a) Computed tomographic scan of the mediastinum demonstrates a mass compressing the trachea and superior vena cava. (b) Radiograph of superior vena cava shows stenosis. (c) Four stents were placed in the superior vena cava (arrows) and one stent in the distal trachea to support the myocutaneous graft (arrowheads; see text). Immediate symptomatic relief was noted after stent placement. (d) Pathologic specimen shows the stents in the superior vena cava, which is encased by tumor (arrows). Superior vena cava was patent with no clot formation.

of the veins that were bridged by the stent remained patent.

In the other three dogs, the stents failed to dilate the stenotic vena cava and resulted in occlusion. In the first of these three dogs, an attempt was made to place the stent across an occluded inferior vena cava. The stent could not reestablish the lumen but perforated the inferior vena cava, which resulted in retroperitoneal abscess. In the remaining two, attempts to place the barbless stents across the right stenosis were complicated by migration as the stents were released from the catheter. The stents formed a cone with the distal end expanded in the normal inferior vena cava and the proximal end closed in the stenotic portion (Fig. 3). This closed, proximal end obstructed blood flow, resulting in thrombus formation.

CLINICAL APPLICATION

Case 1

Severe stridor and a superior vena cava syndrome developed in a 42-year-old woman secondary to a poorly differentiated carcinoma of the trachea involving the mediastinum that did not respond to radiation therapy. Surgical debulking was attempted to alleviate her symptoms. The distal trachea was partially resected and reconstructed with a myocutaneous graft. However, the myocutaneous graft collapsed with each inspiration, and the patient required the assistance of a positive pressure respirator to breathe. The superior vena cava syndrome persisted.

Superior cavography demonstrated stenosis of both innominate veins and the superior vena cava at their injunction. An attempt to dilate the stenosis with two angioplasty balloon (9-mm-diameter) catheters was not successful.

Four regular barbless stents, each 3 cm in diameter and 3-cm long, were placed in the right innominate vein and superior vena cava (Fig. 4). Another stent was placed into the distal trachea to prevent the collapse of the myocutaneous graft.

After stent placement, there was immediate relief of the superior vena cava syndrome, and the patient was able to breathe without assistance. Systemic chemotherapy was instituted but resulted in severe myelosuppression and sepsis. She died 3 weeks later. At autopsy, the superior vena cava was patent, and no clot formation was seen on the stents. The tracheal stent maintained the patency of the myocutaneous graft.

Case 2

An 82-year-old woman was admitted with edema of both legs and the lower abdomen. She had had a retroperitoneal leiomyosarcoma that had been treated with surgical resection and radiation therapy 8 years prior. She also had had chronic pancreatitis and retroperitoneal fibrosis that necessitated a choledochojejunostomy to relieve an obstructive jaundice 8 months before she was admitted with edema.

Inferior cavography demonstrated a marked stenosis of the vena cava at the level of L-4 with paravertebral collaterals. The pressure gradient across the stenosis was 20 cm of saline.

Table 2
Effect of Stents on Pressure Gradients (cm of saline)

Dog	Before Stent	After Stent	4 Months Later
1	NS	NS	...
2	5	2	2
3	8	1	1
4	6	3	2

Note.—NS = not significant.

Three barbless stents, each 2.5 cm in diameter and 3-cm long, were placed across the stenosis (Fig. 5). Immediately after stent placement, the pressure gradient was reduced to 10 cm of saline. However, one stent migrated and lodged in the hepatic segment of the inferior vena cava. On the next day that stent migrated into the right ventricle, necessitating the placement of a bird's nest filter in the inferior vena cava to prevent migration of the other stents. Additional stents with a larger diameter (3 cm) were placed across the stenosis.

The edema of the legs disappeared and did not recur. The patient experienced no clinical problems related to the stent lodged in the ventricle. She died 5 months later with progressive disease in the retroperitoneum and abdomen. At autopsy, the inferior vena cava (encased by the recurrent tumor) was widely patent, maintained by the stents, and was free of clot formation. The stent in the right ventricle was covered by endocardium with no clot formation.

DISCUSSION

The results of this animal experiment and limited clinical experience should be interpreted with caution. It appeared that in both the women and the dogs the stents had not expanded to their fullest diameters or to the original diameters of the vena cavas. However, they had allowed enough blood flow through the stenoses to decrease the pressure gradients. In case 2, the expansile force of the stent not only immediately neutralized or relieved the extrinsic compression from fibrosis or tumor in the vessel wall but also prevented progression of the stenosis.

The stents failed when they were placed in a thrombotic or occluded vessel. The presence of blood clot or intraluminal tumors may limit the use of the Gianturco stent. An intraluminal tumor will probably grow around the wires of the stent. Lysis of the blood clot by thrombolytic agents could be helpful before stent placement. Placement of the stent into a tight stenotic lesion may not adequately expand the lumen to allow sufficient blood flow, which would result in thrombosis. In such instances, balloon dilatation before stent placement should be considered.

Early migration of the stents occurred in two dogs. When released from the catheters, the stents tended to spring into the nonstenotic portion of the vessel and formed a cone, the narrowed end of which obstructed blood flow and resulted in thrombosis. To avoid early migration, double stents and barbed stents were used. As the leading stent was released from the catheter, the other remained within it, which allowed slight manipulation or change in position and thus better stabilization.

The stent in case 2 most likely migrated because the size of the inferior vena cava was underestimated. As demonstrated on the radiograph of the inferior vena cava obtained before stent placement, the caval diameter above the stenosis was only 1.2 cm, compared with the diameter of 2.5 cm after placement of the stents. Thus, a 2.5-cm diameter stent was apparently too small. To prevent such migration, the selection of the proper stent diameter and use of a barbed stent are recommended for fixation of the stent to the caval wall.

The expansile force of the stent increases with an increase in the caliber of the wire, in stent diameter, and in the number and angle of wire bends. However, an increase in length will decrease the expansile force. The expansile mechanism and the introduction of the Gianturo stent are much simpler than those of grafts made of nitinol wire. It spontaneously returns to its original shape after release without the changes in temperatures required in use of nitinol wire. Its expansile mechanism is also simpler than that of the Palmaz graft, which uses an angioplasty balloon to expand the graft. The ability of the Gianturco stent to expand slowly over time may also offer an advantage over the other types of stents.

Conventional treatment for stenosis of the vena cava secondary to tumor encasement is radiation therapy or chemotherapy (5–8). Successful relief of superior vena cava syndrome has been reported in as high as 94% of patients. Resolution of the signs and symptoms may have a latent period up to 3 weeks (5). For stenosis from surgical or postradiation fibrosis, the treatment is more difficult. Bypass surgery or surgical correction is considered a major undertaking and may not be worth the effort, particularly in patients who still have residual or recurrent tumor (9).

Clinical application of the Gianturco stent seems appropriate for further investigation, particularly in patients with a vena cava that is stenotic because of encasement from a tumor that has not responded to radiation therapy or chemotherapy or because of postsurgical and radiation fibrosis. ■

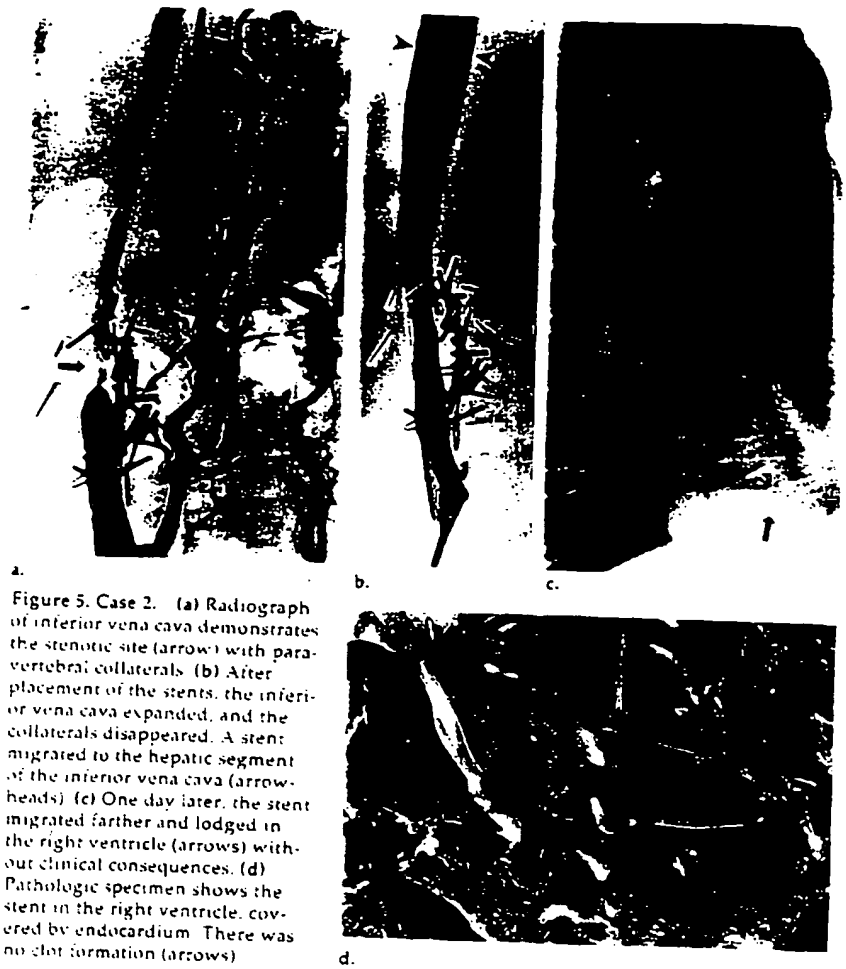


Figure 5. Case 2. (a) Radiograph of inferior vena cava demonstrates the stenotic site (arrow) with paravertebral collaterals. (b) After placement of the stents, the inferior vena cava expanded, and the collaterals disappeared. A stent migrated to the hepatic segment of the inferior vena cava (arrowheads). (c) One day later, the stent migrated farther and lodged in the right ventricle (arrows) without clinical consequences. (d) Pathologic specimen shows the stent in the right ventricle, covered by endocardium. There was no clot formation (arrows).

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Flexible Balloon-expanded Stent for Small Vessels

Work in Progress[1]

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A new type of flexible, balloon-expanded, stainless steel stent was designed for introduction into small vessels subject to motion. Four stents placed in four dogs were patent at follow-up (4–8 weeks). A fibrocellular proliferation involving the intima and media was responsible for a 20%–25% luminal narrowing observed in all vessels with stents. The stent has longitudinal flexibility, which should permit its insertion into small peripheral, visceral, and coronary arteries.

Index term: Arteries, grafts and prostheses

Radiology 1987; 162:276–278

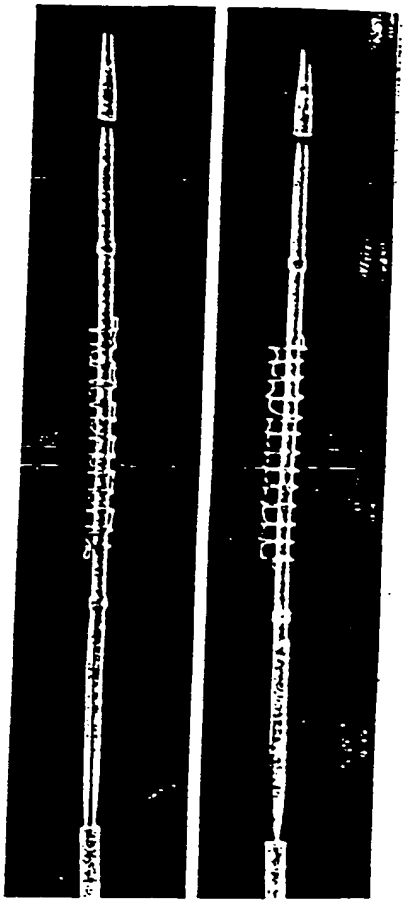
ENDOVASCULAR stents may be useful for correcting severe intimal dissection or recurrent stenosis after angioplasty of small vessels. Many types of endovascular stents and prostheses are described in the literature, but few have been inserted in vessels smaller than 5 mm and none have longitudinal flexibility. Only two of six coiled, stainless steel wire stents (3.5 mm in diameter) placed in canine arteries remained patent at follow-up (1). The insertion of two nitinol wire coils (5 mm in diameter) resulted in thrombosis of one coil after 2 weeks and significant narrowing of the lumen within the other coil after 13 weeks (2). Self-expanding, zigzag (Gianturco) metallic stents inserted in vessels smaller than 5 mm remained patent provided the ratio of stent/recipient vessel diameter was smaller or equal to 1.2 (3).

This report describes a new type of flexible, balloon-expanded endovascular stent. The technique of insertion and the preliminary results in vessels smaller than 5 mm in diameter are presented.

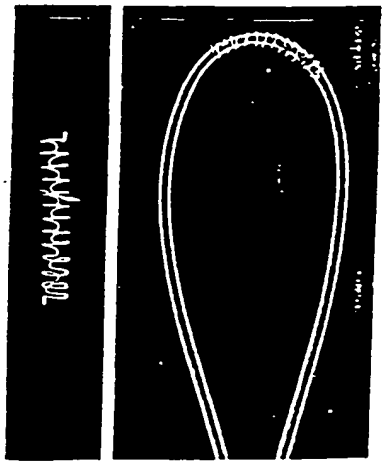
Materials and Methods

The flexible, balloon-expanded stents were made of surgical suture wire (0.006-inch) wrapped cylindrically, with bends adopting a sequential U and inverted U configuration every 360° (Fig. 1). The stents were wrapped tightly around a collapsed angioplasty balloon (25 mm long and 2.5 mm in diameter when fully inflated). The angioplasty balloon–stent unit was 2 mm in diameter; when fully expanded, stents measured 15 mm long and 2.5 mm in diameter. To evaluate longitudinal flexibility, the stents were wrapped around 5-F polyethylene tubing that had been bent into various configurations (Fig. 2).

Four adult mongrel dogs (20–24 kg) were anesthetized with an intravenous injection of sodium pentobarbital (30 mg/kg). After heparin administration (100 U/kg), a vessel with a diameter similar to that of the stent was selectively catheterized using a 5-F polyethylene catheter; the catheter was introduced through a carotid arteriotomy. Catheter exchange was performed over a wire guide (0.018 inch), and the angioplasty balloon–stent unit was advanced to the area of interest. The balloon was inflated to maximal pressure for 1 minute. This was repeated two to three times until good stent expansion was observed fluoroscopically. The angioplasty catheter was withdrawn while negative pressure was applied to the balloon. Angiography was performed before and immediately after stenting, at 1 week, 4 weeks, and at the end of the study. One stent was inserted into the gluteal, saphenous, superficial femoral, or deep femoral artery



1a. 1b.



1c.

Figures 1, 2. (1) Low-kV radiographs with two-fold magnification. (a) Angioplasty balloon–stent unit in the collapsed state. The stent fits tightly around the angioplasty balloon between the metallic markers. (b) Angioplasty balloon–stent unit after inflation to maximal pressure. Complete expansion of the stent is seen. (c) Expanded stent after the angioplasty balloon is withdrawn. (2) Low-kV radiograph. After balloon expansion, the stent has been mounted on a 5-F, bent, polyethylene catheter.

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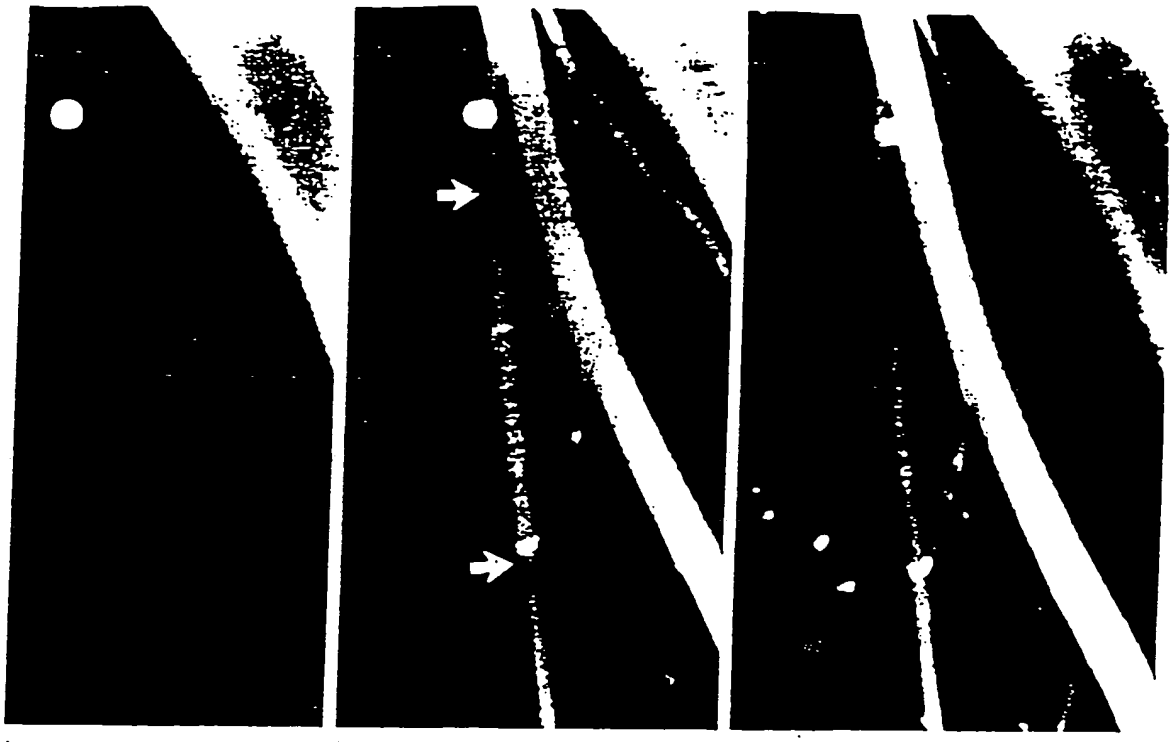

a. b. c.

Figure 3. Collimated views of conventional radiograph (a) and superficial femoral arteriogram (b) obtained immediately after stent insertion in the left saphenous artery. The stent is fully expanded, and the vessel lumen is patent. Note dilatation of the artery at the site of balloon inflation (arrows). b) (c) Arteriogram obtained 6 weeks after insertion demonstrates a 25% luminal narrowing within the stent. The stent diameter is unchanged, and there is slight luminal narrowing at the origin of one small side branch.

Figure 4. Longitudinal section of a stented artery 6 weeks after placement (Hematoxylin and eosin, ×100.) Note proliferation of intima and disruptions of the internal elastic lamina (open arrows). There is also a fibrocellular proliferation involving the media. Double-headed arrow indicates the endothelium-lined space occupied by the stent wire. The side branch seen to the right of this space is patent.

one stent per dog). The dogs were killed by exsanguination while under deep sodium pentobarbital anesthesia at 2 weeks (two dogs), 3 weeks (one dog), or 6 weeks (one dog). The vessels containing the stents were resected and examined grossly and histologically.

Results

These flexible stents were easily expanded to their full diameter (2.5 mm) and did not change in diameter during the follow-up period (4–8 weeks). All stents were patent immediately after insertion. A 20%–25% luminal narrowing was observed in all stents at the end of the follow-up period (Fig. 3). No vessel occlusion or stent migration was noted. Blood vessels bridged by the stents remained patent with no evidence of narrowing, except in one case in which a small branch narrowed slightly at its origin (Fig. 3c).

Histologic examination showed multiple disruptions of the internal elastic membrane and occasional intimal splits with associated areas of intimal hemorrhage (Fig. 4). A moderate proliferation of intimal cells was noted, as was a cellular proliferation involving the media. These proliferations were predominantly fibrocellular. All stent wires were embedded in intimal proliferation and covered by a thin endothelial layer on the luminal surface. No thrombosis was seen, and the adventitia remained intact.

Discussion

Our results demonstrate that this type of stent can easily be introduced into arteries less than 3 mm in diameter and that complete stent expansion can be achieved with an angioplasty balloon. Successful insertion required gentle introduction of the angioplasty balloon–stent unit at the arteriotomy site to prevent the stent from slipping off the balloon. Three balloon inflations at maximal pressure were necessary to achieve full stent expansion and avoid difficulty in withdrawing the balloon.

One definite advantage of this balloon-expanded stent is its longitudinal flexibility. The tubular mesh described by Palmaz et al. (4) is also expanded by an angioplasty balloon, but it lacks longitudinal flexibility. We have also succeeded in inserting the self-expanding zig-zag stents into straight vessels smaller than 3 mm, but this stent has no longitudinal flexibility either (3). This flexibility is important if stents are to be inserted into small, continuously moving vessels with numerous curves and bends, such as the coronary arteries. Flexible stents should also be useful in extremity, gastrointestinal tract, and renal arteries.

PX207

Angioplasty often results in splitting of the intima to the level of the internal elastic membrane and intimal hemorrhage (5, 6) as was seen in this study. In addition, the stents remained patent with no occlusion of side branches, but 20%–25% luminal narrowing occurred in all stented vessels. This was attributable to a fibrocellular proliferation involving both the intima and the media, which may represent stent-enhanced continuation of the vascular repair process initiated by angioplasty. The hemodynamic significance and the long-term (>8 weeks) outcome of these changes are not known. Further, these results were obtained in normal vessels, and additional studies are needed to determine the effects of balloon-expanded stents in experimentally induced stenotic lesions. ■

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Normal and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting[1]

Elastic recoil of the vessel wall is a common cause of failure of percutaneou transluminal angioplasty in renal arteries. To oppose such recoil, balloon-expandable metal stents were implanted in artificially stenotic renal arteries in pigs and normal renal arteries in dogs and pigs. The stents were then examined angiographically and histologically at regular intervals. All stents were comp letely covered with endothelialized neointima in 3 weeks. There was no difference in intimal thickness between the stenotic and nonstenotic renal arteries. A large stent diameter and a large open or nonmetal surface may cause less intimal hyperplasia, but nonturbulent, fast arterial flow is probably the most imp tant factor in ensuring long-term patency of the vessel.

Index terms: Arteries, grafts and prostheses, 961.128 • Arteries, interventional procedure, 961.128 • Arteries, stenosis, 961.721 • Catheters and catheterization, technology • Renal arteries, interventional procedure, 961.128 • Renal arteries, stenosis, 961.721

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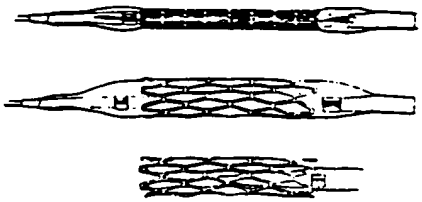

Figure 1. Collapsed balloon-mounted stent (top), expanded stent (center), and stent in place while deflated balloon is withdrawn (bottom).

ALTHOUGH percutaneous transluminal angioplasty (PTA) for renal artery stenosis is widely used clinically, its efficacy is limited in certain types of renal artery lesions. Atherosclerosis, the most common cause of renal artery stenosis, does not respond well to angioplasty. In general, for hypertension caused by atherosclerotic renal artery stenosis, cures 1–2 years after PTA average only 21%. Improvement without cure in the same period nears 60% (1–3). PTA is usually not successful in patients with atherosclerotic stenosis at the renal artery ostium and in those with bilateral renal artery disease (4, 5). Only two-thirds of patients with anastomotic renal artery stenoses occurring after renal transplant receive long-term benefit from angioplasty, and frequently there is residual stenosis at the angioplasty site (6).

A renal PTA leaving significant residual stenosis often fails (4); this emphasizes the need for adequate dilation. The use of balloons with larger diameters to overdilate the stenotic area has been proposed (7), but this increases the risk of renal artery rupture (8).

As a method of opposing elastic recoil after balloon dilation without overdilating, we investigated the application of balloon-expandable metal stents in pigs with artificial renal artery stenoses. We compared the results with those obtained after stent placement in normal renal arteries of pigs and dogs. This research focused on the mechanics of simultaneous dilation of the stent and the artery and on the long-term effects of the implanted device on the renal artery and the renal parenchyma, determined with histologic and morphometric analysis.

MATERIALS AND METHODS

Characteristics of the Stent

The stent is a modified version of the same meshlike design used previously (9) (Fig. 1). It still has a nonexpanded diameter of 1.67 mm, a length of 15 mm, and a wall thickness of 0.076 mm. The new stent, however, has six double rows of staggered slots, instead of eight, and has narrower struts. These modifications reduce the total metal surface, while maintaining critical physical properties:

1. Free area and dimensional changes. The free or open area of the stent ranges from 69% in the collapsed state to a maximum of 88% at 6 mm in diameter. With expansion, the slots in the wall assume a diamond shape; thus the open area increases until all four corners of the diamonds have equal angle. Expansion beyond this point results in a decrease of the open area. The length of the stent decreases as the diameter increases. Figure 2 shows that for a given stent configuration, there is an optimal range of expansion.

2. Balloon and stent expansion characteristics. When a carrier balloon requiring 10 atm of pressure to achieve its nominal diameter is used, 88% of total stent expansion occurs at 4.5 atm. Beyond that point, no significant increase in pressure is needed to produce complete expansion of the balloon-stent assembly, compared with the balloon alone. Therefore, the additional stress imposed on the balloon by the coaxially mounted stent occurs at the low end of the pressure curve, far from the bursting limit of the balloon (Fig. 3).

3. Response of the stent to external pressure. This was tested by applying a collarlike device, constructed to allow a uniform pressure to be generated over the surface of the stent by suspending weights from the free end of the device.

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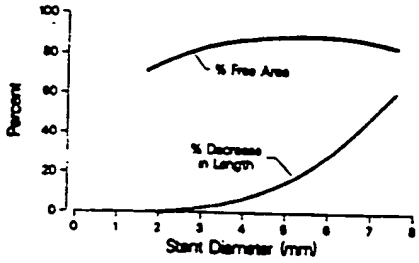
See also the article by Rousseau et al. (pp. 709-714) in this issue.



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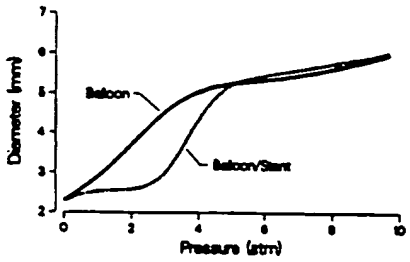

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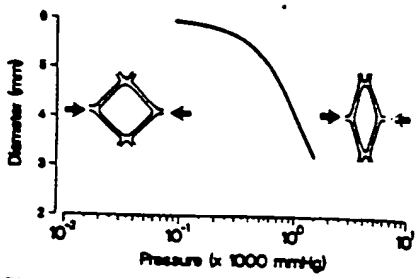

Figures 2, 3. (2) Percentage change in free area and decrease in length as a function of stent diameter (e.g., from 3 to 5 mm in diameter, open area increases 5.7% while length decreases 12.1%). (3) Pressure and diameter changes in 6-mm angioplasty balloon, alone (solid line) and in combination with a coaxially mounted stent (broken line).

Figure 4. Change in stent diameter as a function of circumferential pressure. The arrows indicate the direction of force applied to the diamond-shaped spaces of the mesh.

The weights created a circumferential stress in the collar and an external pressure on the expanded stent. The stress developed in the collar wall by the weights is given by $S = W/(t \cdot L)$, where S is the circumferential or hoop stress, W is the suspended weight (in grams), t is the thickness of the collar wall (in centimeters), and L is the length of the collar (in centimeters).

The relationship (10) between the circumferential stress S and the pressure P for thin-walled cylinders of radius R (in centimeters) is $S = (P \cdot R)/t$. From these equations the relationship sought is $P = W/(R \cdot L) = (2 \cdot W)/(D \cdot L)$, where D is the stent diameter (in centimeters). This relationship was used to calculate wall pressure for a series of suspended weights ranging from 0 to 1,500 g. All pressures were expressed in millimeters of mercury for easy comparison with intraluminal vascular pressures. Figure 4 shows that the fully expanded stent is stronger at maximum expansion than at smaller diameters. This is because the force from the externally applied wall pressure can be resolved into two components, one directed along the struts of the stent and one perpendicular to them. The larger the stent diameter, the greater is the component of force along the struts; therefore, the stent resists circumferential force more effectively.

Experimental Methods

Preparation of the renal artery stenosis model.—Eleven adult minipigs weighing 75–180 lb (34–81 kg) underwent midline laparotomy under general gaseous anesthesia. Subocclusive stenosis was created in the right mid-renal artery by placing a 1-0 polydioxanone suture (Ethicon, Somerville, N.J.) around the artery and a piece of 6-F Teflon tubing alongside the artery. The tubing served as a tool to achieve uniform slack in the suture. After the ligature was tied and the tubing removed, renal artery patency was confirmed by the presence of pulsations distal to the ligature. The pigs were fed a diet that kept them at a steady weight after surgery. In 6 months, renal artery stenosis had developed in all the pigs. Ischemic atrophy of the kidney developed in three pigs, but the renal arteries remained patent. In two of the three, the degree of atrophy was severe; the renal arteries were thready and therefore unsuitable for stenting. The stenoses resulting from the resorbable sutures were focal and ranged from 13% to 50% of the proximal renal artery lumen (Fig. 5a). In three animals, the stenoses were minimal, ranging from 13% to 17%. In animals with the stent placed in the opposite normal renal artery, histologic examination of the stenotic area showed an organized thrombus at the site of suture placement, overlying a folded and interrupted internal elastic lamina (Fig. 5b). This thrombus, with focal myointimal proliferation and adventitial fibrosis, caused the focal narrowing of the renal artery.

a. b.

Figure 5. (a) Abdominal aortogram in a pig, 6 months after subocclusive ligature of the right renal artery. (b) Cross section of a pressure-fixed, stenotic renal artery in a pig 6 months after subocclusive ligation. Internal elastic lamina (arrows) appears folded and redundant as a result of the peripheral constrictive adventitial fibrosis. Intimal thickening probably represents organized thrombus. (Hematoxylin and eosin; original magnification ×58.)

Stenting procedure.—Six months after ligature, general gaseous anesthesia was administered to each pig, the right femoral artery was exposed, and an introducer sheath was placed in it. The stents were coaxially mounted over angioplasty balloon catheters with a 5-mm-diameter balloon and were manually crimped in place. The catheters with the mounted stent were steered to the target over a 0.016-inch steerable guide wire after the initial placement of a selective 6-F catheter in the ostium of the renal artery. A Y connector (USCI, Billerica, Mass.) allowed test injections of contrast material during manipulation of the catheter and wire.

One hundred seventy-five milligrams of aspirin and 25 mg of dipyridamole were given the day before and up to 3 months after the procedure. Fifty units of heparin per kilogram and 250 ml of 40% low-molecular-weight dextran were given intravenously during the procedure. The stenotic artery was not stented in the two pigs that had atrophic, shrunken kidneys as a result of the ligature placement; in two in which severe arterial spasm developed during catheter manipulation; and in one that had a narrow angle between the renal artery and the aorta. Rather, the stent was placed in the contralateral renal artery, and these five animals were used as controls.

Eight dogs weighing 35–55 lb (16–25 kg) underwent left carotid arteriotomy while under general gaseous anesthesia. After placement of a 9-F introducer sheath in the carotid artery, a baseline abdominal aortogram was obtained. Insertion of the expandable stent was accomplished with materials and methods similar to those used in pigs.

Dogs and pigs were killed in groups and at intervals indicated in Table 1. The methods used for the histopathologic preparation of the stented arteries was the same as reported previously (9). Factor VIII–related antigen was assayed in the endothelial surface of the stents with the immunoperoxidase method (11).

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Figures 6, 7. perimental s ly sectioned. weeks after microscope i

Table 1 Maximum

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Pig

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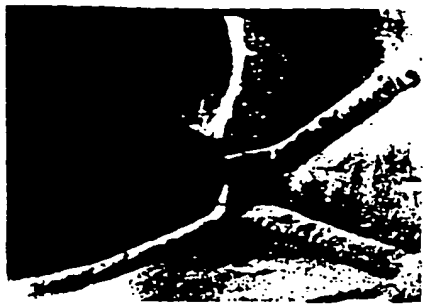

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Figures 6, 7. (6) Gross specimen of pig kidneys 24 weeks after stent placement in the experimental stenosis of the right renal artery. Kidneys, renal arteries, and aorta were coronally sectioned. (7) Scanning electron micrograph of the inner surface of a renal artery stent 24 weeks after placement (original magnification ×40). The central circle indicates high-power microscope insert site (original magnification ×240).

Table 1
Maximum Follow-up of Stented Renal Arteries

	Pigs		
Weeks	with Stenosis	without Stenosis	Dogs
1	2	2	2
3	2	1	2
8	1	1	2
24	1	1	2

RESULTS

Pig

Si renal artery stenoses were successfully stented and the lumen diameter completely restored (Fig. 6). At 1 week, low-power microscopic examination of the inner surface of the stented renal arteries showed partial coverage of the inner stent lumen with endothelialized neointima. Specimens 3 weeks and older were completely covered with intimal tissue. Cross-sectional specimens taken at 1 week and prepared with hemotoxylin and eosin and metachromatic stain showed an accumulation of red cells in the troughs formed between the struts and the depressed inner arterial surface. By 3 weeks the clot had almost completely disappeared, and the struts were covered with endothelialized neointima. In specimens 8 weeks and older, complete resorption of the red cells and pigments under the thin neointima caused the inner surface of the stent to look like a bas-relief of the stent (Fig. 7). A 5-mm stent placed in a 3-mm renal artery with moderate ischemic atrophy of the corresponding kidney had a neointimal thickness of 917 μm. This narrowed the lumen of the overdilated stent to the diameter proximal and distal to the stented area. In other words, the neointimal formation modeled the arterial wall, resulting in a uniform lumen diameter. In the five pigs with stented renal artery stenoses and an angiographically normal ipsilateral kidney before stenting, the placed stents had a mean intimal thickness of 58 μm ± 15. In the remaining five pigs with stents placed in the opposite normal renal artery, the stented lumen remained patent and had a mean intimal thickness of 86 μm ± 66.

In the six pigs with stented renal artery stenosis, histologic examination of the renal parenchyma showed no abnormality in five. Mild interstitial fibrosis was present in the single kidney that showed a moderate degree of atrophy on angiography done before stenting. The two small, scarred kidneys that were unsuitable for stent placement had severe diffuse parenchymal fibrosis, resulting from severe ischemia at the time of the ligature placement.

Dog

All previously normal stented arteries were patent on radiographic and histopathologic examination. In one instance, a week after placement of a stent in the ostium of a renal artery, the stent partially migrated into the aortic lumen. However, it caused no narrowing of the renal artery lumen, and it did not damage the kidney. The healing pattern of the stent in canine renal arteries was identical to that observed in pigs at each observation. Intimal hyperplasia in the canine stents averaged 63 μm ± 58. Histologic examination of the canine kidneys yielded normal results in all specimens.

Factor VIII-related antigen was identified in all canine and porcine preparations, with the oldest specimens having the strongest staining.

DISCUSSION

Pigs have been used to test the results of balloon angioplasty on artificially induced renal artery stenoses. Stridbeck et al. (12) produced stenoses in renal arteries of pigs by dividing and then suturing renal arteries to create a stenotic anastomosis. Since the results of the procedure depend heavily on the skills of the surgeon, we attempted to simplify the model by tying a slack suture of absorbable material around the renal artery. Polydioxanone was chosen as suture material, because it is slowly absorbed over a period of 6 months in pigs (13). By the end of this time, the adventitial scar tissue should be strong enough to maintain the focal constriction. Our model of renal artery stenosis was only moderately successful, since significant stenotic lesions developed in about half the animals, the rest having no significant stenosis or a small, scarred kidney resulting from severe ischemia.

Neither pigs nor dogs are ideal models for catheter manipulation in the renal arteries, because they have a relatively narrow abdominal aorta. In most of the animals, however, we encountered no difficulties placing the stents when the catheter entry location was chosen according to the angle between the renal artery and the aorta, that is, a carotid approach in dogs and a femoral approach in pigs.

Migration of the stent placed at the ostium of a normal canine renal artery may have been caused by the lack of a stenotic lesion "hugging" it in place. Also, dogs have very mobile kidneys, and movement of the renal artery at the ostium may have caused the migration. Stents for renal artery ostial lesions will have to be longer to give a larger stabilizing surface.

Despite possible differences between canine and porcine clotting and healing mechanisms, the patterns of stent incorporation in the ar-

terial wall were remarkably similar in both species for stents of equal size. All 5-mm stents, at 3 weeks or greater after implantation, were covered with essentially the same degree of intimal hyperplasia in all the animals, the only exception being the stent placed in a small renal artery with a low rate of blood flow. Myointimal thickening occurred only over the struts of the stent, and it was quantitatively minimal.

Healing around the 3-mm and 3.5-mm stents placed in the coronary arteries of dogs (14) was different from that around the 5-mm renal stents. In coronary stents, although lumen patency was excellent, the intimal tissue covered the struts and the spaces between adjacent struts in a continuous fashion. Although the free surface difference between the 3-mm and 5-mm stents is only 6%, it may be at least partially responsible for the differences observed. Unfavorable volume-surface relationships of the blood circulating through smaller stents, increased turbulence, higher shear rates, or the presence of wave reflections related to compliance mismatch (10) may also influence the healing process; the relative importance of these factors remains to be demonstrated. It has been previously noted that arterial flow affects the degree of intimal proliferation in the stents; intimal thickness was more prominent in low-flow situations (15). When the expanded stent diameter exceeded that of the target vessel, intimal growth narrowed the stent lumen to match the inflow and outflow portions of the vessel. Whether this will occur in humans remains unknown, but a similar phenomenon has been observed in surgically placed bypass grafts. When a synthetic bypass conduit is exposed to circulating blood, the amount of thrombus deposition is also inversely related to the blood-flow velocity (16). This tends to be a self-limiting process; at low flow rates, thrombus grows until narrowing of the graft lumen results in an increase of the flow velocity to a level above the thrombogenic threshold. From these observations, we believe that the placement of metallic stents in human vessels with low flow rates will have to be approached with caution because of the risk of thrombotic occlusion or excessive intimal growth.

Endothelial cells were identified morphologically with scanning electron microscopy and by the presence of intracytoplasmic factor VIII–related antigen, which is a tissue-specific marker for vascular endothelium (11). Complete endothelialization of the expandable stents at 3 weeks is the reason for the small amount of intimal hyperplasia. Valuable experience in the use of metallic arterial stents in humans has been accumulated in Europe; Sigwart et al. (17) have placed a number of woven stainless steel wire stents in coronary arteries and in peripheral vessels with good short-term follow-up results. Growing interest in this therapeutic approach will undoubtedly result in more human trials. ■

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Flexible Balloon-expanded Stent for Small Vessels

Work in Progress[1]

Gerard Duprat, Jr., MD, FRCP(C)[2]
Kenneth C. Wright, PhD
Chusilp Charnsangavej, MD
Sidney Wallace, MD
Cesare Gianturco, MD

A new type of flexible, balloon-expanded, stainless steel stent was designed for introduction into small vessels subject to motion. Four stents placed in four dogs were patent at follow-up (4-8 weeks). A fibrocellular proliferation involving the intima and media was responsible for a 20%-25% luminal narrowing observed in all vessels with stents. The stent has longitudinal flexibility, which should permit its insertion into small peripheral, visceral, and coronary arteries.

Index term: Arteries, grafts and prostheses

Radiology 1987; 162:276-278

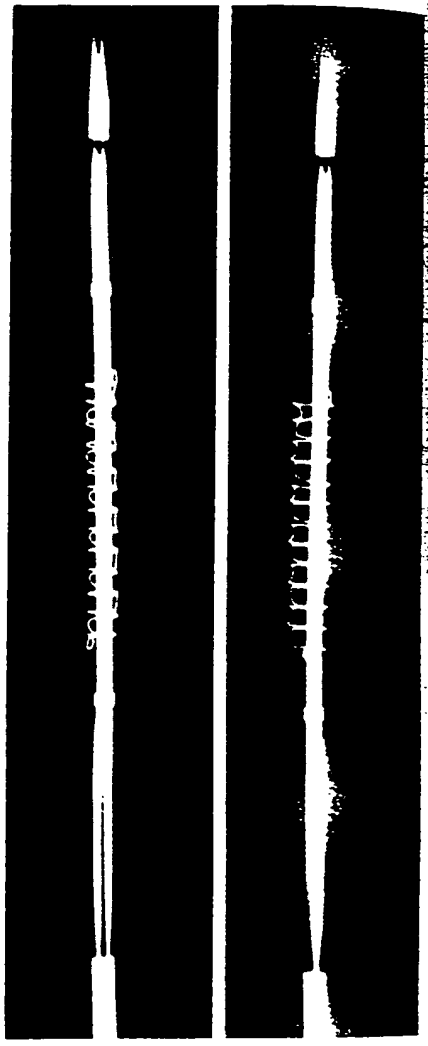
ENDOVASCULAR stents may be useful for correcting severe intimal dissection or recurrent stenosis after angioplasty of small vessels. Many types of endovascular stents and prostheses are described in the literature, but few have been inserted in vessels smaller than 5 mm and none have longitudinal flexibility. Only two of six coiled, stainless steel wire stents (3.5 mm in diameter) placed in canine arteries remained patent at follow-up (1). The insertion of two nitinol wire coils (5 mm in diameter) resulted in thrombosis of one coil after 2 weeks and significant narrowing of the lumen within the other coil after 13 weeks (2). Self-expanding, zigzag (Gianturco) metallic stents inserted in vessels smaller than 5 mm remained patent provided the ratio of stent/recipient vessel diameter was smaller or equal to 1.2 (3).

This report describes a new type of flexible, balloon-expanded endovascular stent. The technique of insertion and the preliminary results in vessels smaller than 5 mm in diameter are presented

Materials and Methods

The flexible, balloon-expanded stents were made of surgical suture wire (0.006-inch) wrapped cylindrically, with bends adopting a sequential U and inverted U configuration every 360° (Fig. 1). The stents were wrapped tightly around a collapsed angioplasty balloon (25 mm long and 2.5 mm in diameter when fully inflated). The angioplasty balloon-stent unit was 2 mm in diameter; when fully expanded, stents measured 15 mm long and 2.5 mm in diameter. To evaluate longitudinal flexibility, the stents were wrapped around 5-F polyethylene tubing that had been bent into various configurations (Fig. 2).

Four adult mongrel dogs (20-24 kg) were anesthetized with an intravenous injection of sodium pentobarbital (30 mg/kg). After heparin administration (100 U/kg), a vessel with a diameter similar to that of the stent was selectively catheterized using a 5-F polyethylene catheter; the catheter was introduced through a carotid arteriotomy. Catheter exchange was performed over a wire guide (0.018 inch), and the angioplasty balloon-stent unit was advanced to the area of interest. The balloon was inflated to maximal pressure for 1 minute. This was repeated two to three times until good stent expansion was observed fluoroscopically. The angioplasty catheter was withdrawn while negative pressure was applied to the balloon. Angiography was performed before and immediately after stenting, at 1 week, 4 weeks, and at the end of the study. One stent was inserted into the gluteal, saphenous, superficial femoral, or deep femoral artery



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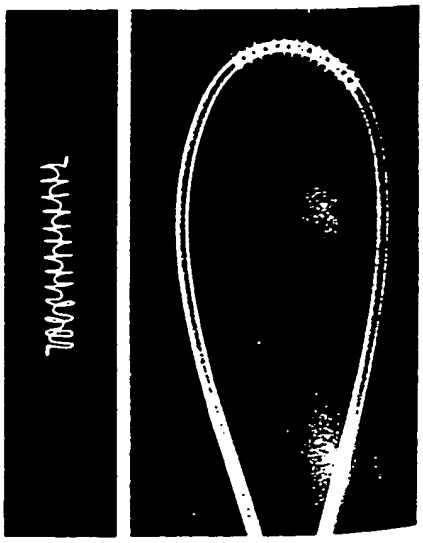

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Figures 1, 2. (1) Low-kV radiographs with two-fold magnification. (a) Angioplasty balloon-stent unit in the collapsed state. The stent fits tightly around the angioplasty balloon between the metallic markers. (b) Angioplasty balloon-stent unit after inflation to maximal pressure. Complete expansion of the stent is seen. (c) Expanded stent after the angioplasty balloon is withdrawn. (2) Low-kV radiograph. After balloon expansion, the stent has been mounted on a 5-F, bent, polyethylene catheter.

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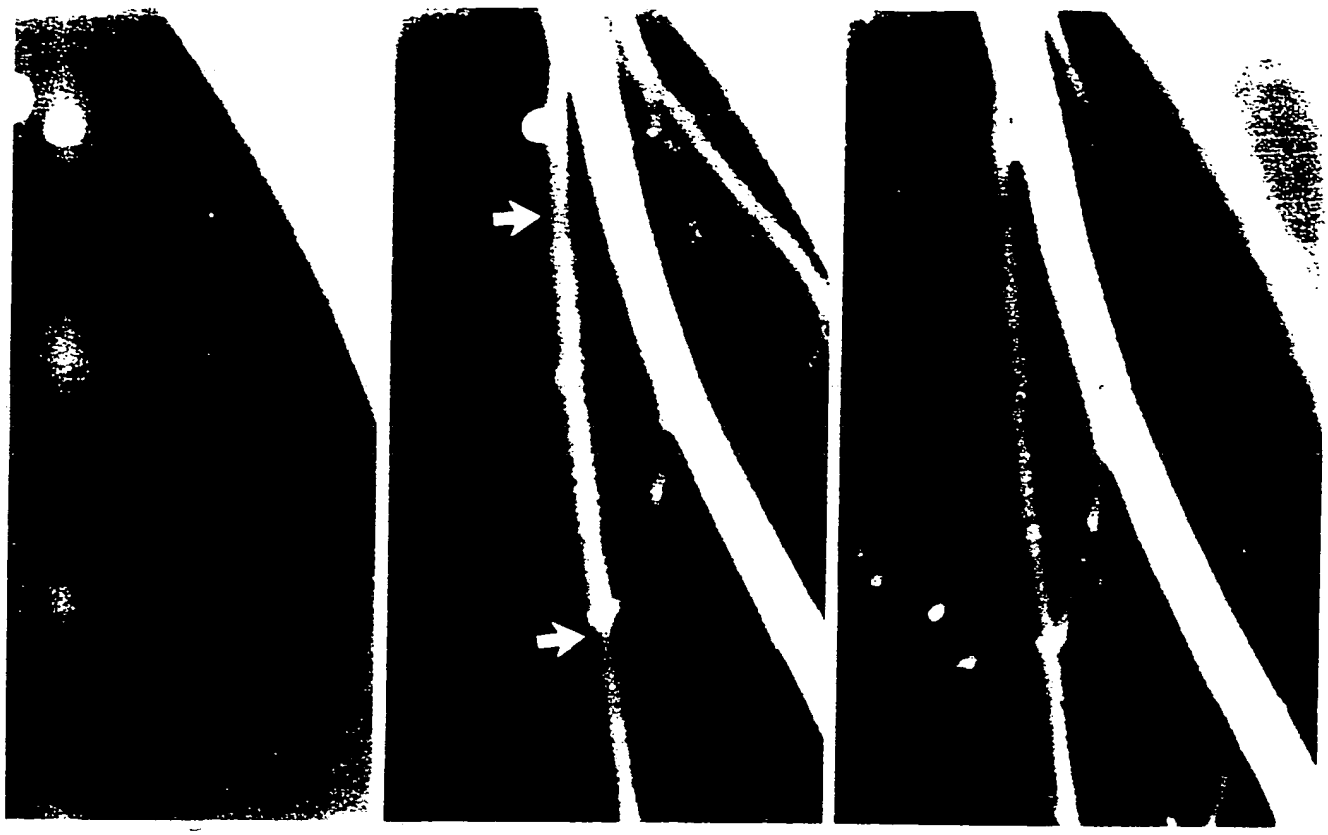

a. b. c.

Figure 3. Collimated views of conventional radiograph (a) and superficial femoral arteriogram (b) obtained immediately after stent insertion in the left saphenous artery. The stent is fully expanded, and the vessel lumen is patent. Note dilatation of the artery at the site of balloon inflation (arrows, b). (c) Arteriogram obtained 6 weeks after insertion demonstrates a 25% luminal narrowing within the stent. The stent diameter is unchanged, and there is slight luminal narrowing at the origin of one small side branch.

Figure 4. Longitudinal section of a stented artery 6 weeks after placement. (Hematoxylin and eosin, ×100.) Note proliferation of intima and disruptions of the internal elastic lamina (open arrows). There is also a fibrocellular proliferation involving the media. Double-headed arrow indicates the endothelium-lined space occupied by the stent wire. The side branch seen to the right of this space is patent.

one stent per dog). The dogs were killed by exsanguination while under deep sodium pentobarbital anesthesia at 4 weeks (two dogs), 6 weeks (one dog), or 8 weeks (one dog). The vessels containing the stents were resected and examined grossly and histologically.

Results

These flexible stents were easily expanded to their full diameter (2.5 mm) and did not change in diameter during the follow-up period (4–8 weeks). All stents were patent immediately after insertion. A 20%–25% luminal narrowing was observed in all stents at the end of the follow-up period (Fig. 3). No vessel occlusion or stent migration was noted. Blood vessels bridged by the stents remained patent with no evidence of narrowing, except in one case in which a small branch narrowed slightly at its origin (Fig. 3c).

Histologic examination showed multiple disruptions of the internal elastic membrane and occasional intimal splits with associated areas of intimal hemorrhage (Fig. 4). A moderate proliferation of intimal cells was noted, as was a cellular proliferation involving the media. These proliferations were predominantly fibrocellular. All stent wires were embedded in intimal proliferation and covered by a thin endothelial layer on the luminal surface. No thrombosis was seen, and the adventitia remained intact.

Discussion

Our results demonstrate that this type of stent can easily be introduced into arteries less than 5 mm in diameter and that complete stent expansion can be achieved with an angioplasty balloon. Successful insertion required gentle introduction of the angioplasty balloon–stent unit at the arteriotomy site to prevent the stent from slipping off the balloon. Three balloon inflations at maximal pressure were necessary to achieve full stent expansion and avoid difficulty in withdrawing the balloon.

One definite advantage of this balloon-expanded stent is its longitudinal flexibility. The tubular mesh described by Palmaz et al. (4) is also expanded by an angioplasty balloon, but it lacks longitudinal flexibility. We have also succeeded in inserting the self-expanding zig-zag stents into straight vessels smaller than 5 mm, but this stent has no longitudinal flexibility either (3). This flexibility is important if stents are to be inserted into small, continuously moving vessels with numerous curves and bends, such as the coronary arteries. Flexible stents should also be useful in extremity, gastrointestinal tract, and renal arteries.

Angioplasty often results in splitting of the intima to the level of the internal elastic membrane and intimal hemorrhage (5, 6) as was seen in this study. In addition, the stents remained patent with no occlusion of side branches, but 20%–25% luminal narrowing occurred in all stented vessels. This was attributable to a fibrocellular proliferation involving both the intima and the media, which may represent stent-enhanced continuation of the vascular repair process initiated by angioplasty. The hemodynamic significance and the long-term (>8 weeks) outcome of these changes are not known. Further, these results were obtained in normal vessels, and additional studies are needed to determine the effects of balloon-expanded stents in experimentally induced stenotic lesions. ■

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Recurrent Female Pelvic Cancer: Assessment with Transrectal Ultrasonography[1]

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Fifty-two women with symptoms or signs suggesting pelvic recurrence of biopsy-proved pelvic cancer were assessed in a prospective trial by clinical examination, transabdominal pelvic ultrasonography (TAU), computed tomography (CT), and transrectal pelvic ultrasonography (TRU). TRU significantly added to the information from TAU in the measurement of abnormalities on the pelvic sidewalls, and to TAU and CT in the measurement of abnormalities in the central and presacral regions of the pelvis. Results of this preliminary study suggest that TRU may provide information complementary to that from CT in women with suspected recurrence of gynecologic cancer.

Index terms: Pelvis, CT, 8.1211 • Pelvis, neoplasms, 8.32 • Pelvis, US studies, 8.1298

Radiology 1987; 162:278—281

THE diagnosis and assessment of recurrent female pelvic cancer is a challenging problem. Precise determination of tumor dimensions and distribution within the pelvis is an essential prerequisite for rational therapy; however, clinical examination is unreliable (1), and restaging laparotomy may not be indicated in all cases. Transabdominal pelvic ultrasonography (TAU) and computed tomography (CT) have therefore emerged as important pretreatment investigations (2).

Transrectal pelvic ultrasonography (TRU) was designed to assess localized prostatic cancer (3). Subsequent studies demonstrated that images of other pelvic structures could be obtained using low-frequency endosonic transducers (4); this prompted a previous study, the results of which suggested that TRU may be used in the management of recurrent cervical cancer (5). The aims of the present study were to determine the features on TRU of a variety of recurrent gynecologic cancers and to compare TRU findings with those of clinical examination, TAU, and CT.

Patients and Methods

Fifty-two consecutive patients (median age, 52 years; range, 27–68 years) were entered into this prospective trial. All were referred to St. Chads Hospital or the Queen Elizabeth Hospital between June 1984 and March 1985 with symptoms suggesting pelvic recurrence of biopsy-proved pelvic malignancy. The patients represented a selected group referred from several hospitals to a regional center for cancer treatment. Patients had previously been treated for cervical cancer (30 cases; median time since original treatment, 21 months), epithelial ovarian cancer (18 cases, 11 months), endometrial cancer (four cases, 27 months), uterine sarcoma (three cases, 7 months), or bladder cancer (one case, 12 months). Twenty-seven had undergone pelvic surgery (hysterectomy and bilateral salpingo-oophorectomy with or without lymphadenectomy), and 31 had undergone pelvic radiation. Informed consent was obtained from all patients after the nature of the study procedures had been explained.

All patients underwent clinical examinations and TAU; 48 had CT examinations. All patients subsequently underwent TRU examination. Clinical pelvic assessments were performed with patients in the supine position and included abdominal, digital vaginal, rectal, and combined vaginal-rectal examinations. Patients had full bladders for the TAU examinations. Transverse, longitudinal, and oblique scanning was performed with patients supine using 3.5–5-MHz real-time sector transducers coupled to a Hewlett Packard (Andover, Mass.) 77065AR ultrasound (US) scanner. Water enemas were not used.

CT was performed using an International General Electric 8800 CT scanner (Milwaukee) with the dynamic scan option (B7815F dynamic scan software package). Contiguous 1-cm sections were obtained that included the superior margin of the bladder and the level of the pubic symphysis. One hour before CT examination, patients ingested 100–200 ml Gastrografin (10% sodium diatrizoate, 66% meglumine diatrizoate; Schering, Burgess Hill, United Kingdom) diluted in 1–2 litres of water (4% solution vol/vol). Immediately before CT, patients were given 20 mg busco-

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Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents[1]

To test the ability of Gianturco expandable metallic stents to dilate and maintain patency in stenotic venae cavae, stenosis of the inferior vena cava was created in seven mongrel dogs by the percutaneous injection of absolute ethanol into the paravascular retroperitoneal space. Gianturco stents, placed across the stenotic segment, resulted in successful dilatation with improved hemodynamics in four dogs. The stents failed to dilate an occluded vena cava in one dog; in the remaining dogs, stent placement was complicated by early migration and occlusion. Gianturco stents were placed in two patients, one with superior vena cava syndrome and one with retroperitoneal fibrosis that obstructed the inferior vena cava, and resulted in immediate relief of presenting symptoms. These results should be viewed cautiously, but further investigation into the clinical use of the stents is indicated, especially for patients for whom other treatments are difficult.

Index terms: Venae cavae, grafts and prostheses • Venae cavae, stenosis, 569.36

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In recent years, several types of vascular endoprotheses have been developed for vascular uses. Cragg et al. (1) and Dotter et al. (2) used a metallic alloy (nitinol) to form coil grafts; Palmaz et al. (3) developed a balloon-assisted expandable graft with a thin, stainless steel, wire mesh in the wall; and Wright et al. (4) evaluated the expandable metallic stent designed by Gianturco.

The Gianturco expandable metallic stent is constructed of a stainless steel wire bent in a zigzag pattern to form a cylinder. The stent can be compressed and introduced through a Teflon catheter of 8–12 Fr, depending on the caliber of the wire and the diameter of the stent. As the stent is released from the catheter, it expands to its original diameter. The expansile force varies with the caliber of the wire, the diameter and length of the stent, and the number and angle of the bends.

Wright et al. (4), who studied use of the stent in the normal canine vena cava, found that proliferation of the endothelium covered the entire stent after placement. The caval lumen and orifices of caval side branches remained patent during the 6 months of follow-up.

We report our evaluation of the ability of the Gianturco stent to dilate and maintain the patency of experimentally induced stenoses in the vena cava in dogs. We also describe clinical application of the stent in two patients with stenosis of the vena cava caused by tumor encasement or postsurgical and radiation fibrosis.

ANIMAL EXPERIMENT

Materials and Methods

Seven normal mongrel dogs, each weighing 20–25.5 kg, were used. Anesthesia was induced and maintained with sodium pentobarbital (30 mg/kg).

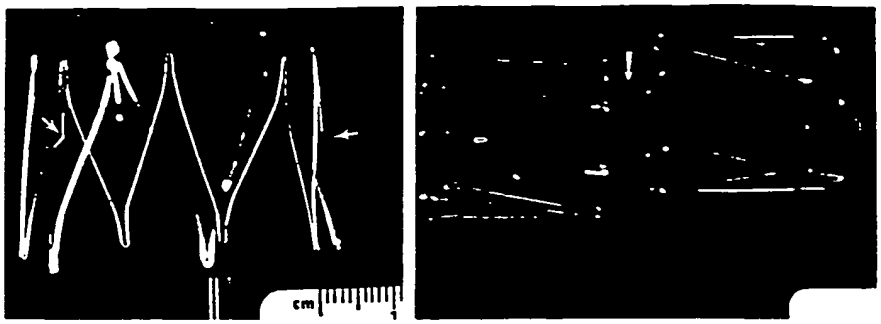
The stenotic vena cava was created by percutaneous injection of 20–30 ml of absolute ethanol through a 22-gauge needle into the retroperitoneal space around the inferior vena cava below the renal veins. Cavography of the inferior vena cava was used to guide the injection and was performed via the femoral or jugular vein approach. We attempted to place the needle tip in the caval wall or the paravascular space rather than in the lumen before the ethanol was injected.

A significant stenosis was defined as a 50% decrease in the caval diameter or a pressure gradient across the stenosis of more than two times normal or 5 cm of saline, whichever was greater. In five of the seven dogs, a significant stenosis developed 2 weeks after the injection. In one dog, stenosis occurred at 1 week, but by 2 weeks, the vena cava was occluded. In the remaining animal, a second injection of ethanol was necessary to achieve caval stenosis in 4 weeks.

After a significant stenosis developed, stents were placed across the narrowed segment. Three types of Gianturco stents were used. In the initial four dogs, a single stent or multiple stents of 0.044-cm (0.018-inch) wire, 2 cm in diameter, and 3 cm long were used. To prevent migration, the stent was modified by attaching barbs (Fig. 1a), which allowed the stent to become affixed to the wall of the vessel as it was released from the catheter. For a long stenosis, two stents of similar length were connected by wire struts (Fig. 1b). They provided a greater expansile force than a single long stent and better stabilization. Migration was minimized by releasing the leading stent while the other stent remained in the catheter.

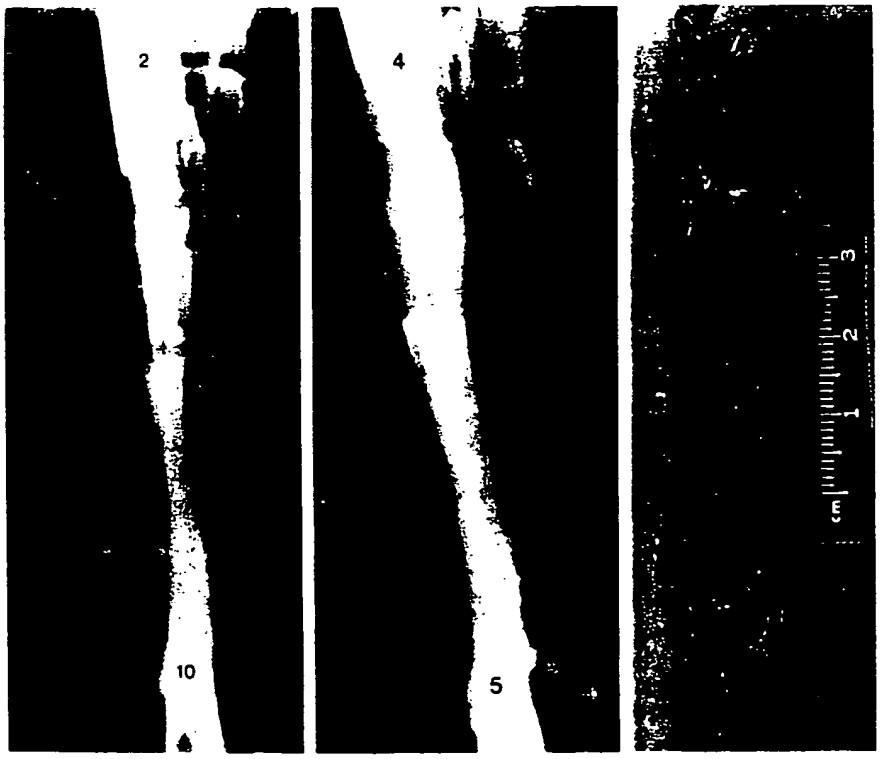
After a 10-F Teflon catheter was positioned at the desired location in the inferior vena cava, the stent was compressed and placed into the hub end. The stent was advanced to the catheter tip with a pusher cable or catheter. To release the stent, the pusher cable was held stable, and the catheter was withdrawn slowly until the stent was completely released and expanded. When multiple stents were placed, an attempt was made to bridge or overlap the adjoining stents. A similar catheter was used to place the barbed stent.

Conventional radiographs of the dogs'



a. b.

Figure 1. (a) Gianturco stent with barbs (arrows). (b) Double stent. Two stents connected by a wire strut (arrow) allow a greater expansile force than a single long stent and provide better stabilization during release.



a. b. c.

Figure 2. Application of stents in experimentally induced caval stenosis in a dog. (Numbers in a and b represent pressure in centimeters of saline.) (a) Stenotic inferior vena cava after injection of absolute ethanol in the retroperitoneum. Pressure gradient across the stenosis was 8 cm of saline. (b) After placement of two single stents, pressure gradient was reduced to 1 cm of saline. (c) Pathologic specimen obtained 4 months after stent placement. The stents were covered by endothelium, incorporating them in the wall of the vessel.

Table 1
Effect of Stents on Inferior Vena Cava Diameter (mm)

Dog	Initial	Stenotic	After Stent Placement: Immediate	After Stent Placement: 4 Months Follow-up
1	16	5	7	9
		7	11	14
2	14	5	8	11
		9	14	14
3	14	5	9	12
4	16	4	7	9
		5	7	9

Note.—Caval diameters were measured at the different stenotic sites in dogs 1, 2, and 4.

a. b.

Figure 3. Failure of the stents. (a) Early migration resulted in a conical stent (arrows). (b) The closed end obstructed blood flow, and thrombosis developed.

abdomens were obtained at 1, 2, 7, and 14 days after stent placement. Inferior cavography and pressure measurements above and below the stenosis were performed at monthly intervals for 4 months. No anticoagulants or antiplatelet agents were given to the dogs during the follow-up period. The dogs were killed when the stents failed or 4 months after placement. Pathologic examination of the retroperitoneum and inferior vena cava was performed.

Results

The stents were successfully placed across the stenosis, and the patency of the experimentally induced stenotic inferior vena cava was maintained in four of the seven dogs. There was an immediate increase in the caval diameter, varying from 2 to 5 mm after stent placement (Table 1). Although the inferior vena cava did not expand to its original diameter or to that of a fully expanded stent, it did expand up to another 3 mm in diameter from the time of placement to the time of sacrifice (Fig. 2). None of the stents migrated.

There was resolution of the pressure gradients in three of the four dogs; one did not have a significant pressure gradient before stent placement. Normal pressure gradients were maintained throughout the 4-month follow-up in all four dogs (Table 2).

Pathologic examination of the inferior vena cava in these four dogs demonstrated the stents to be incorporated in the caval wall (Fig. 2). Endothelial proliferation completely covered the stents in all. There was no clot formation. The orifices

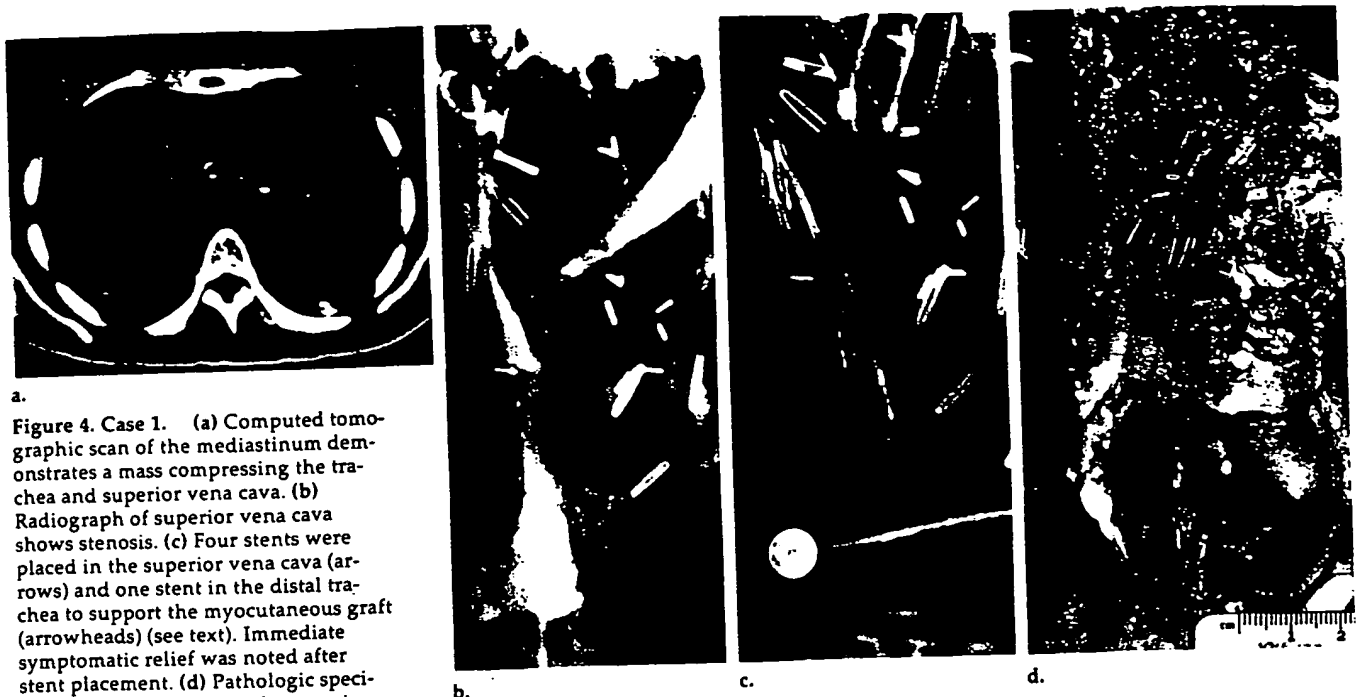


Figure 4. Case 1. (a) Computed tomographic scan of the mediastinum demonstrates a mass compressing the trachea and superior vena cava. (b) Radiograph of superior vena cava shows stenosis. (c) Four stents were placed in the superior vena cava (arrows) and one stent in the distal trachea to support the myocutaneous graft (arrowheads) (see text). Immediate symptomatic relief was noted after stent placement. (d) Pathologic specimen shows the stents in the superior vena cava, which is encased by tumor (arrow). Superior vena cava was patent with no clot formation.

of the veins that were bridged by the stent remained patent.

In the other three dogs, the stents failed to dilate the stenotic vena cava and resulted in occlusion. In the first of these three dogs, an attempt was made to place the stent across an occluded inferior vena cava. The stent could not reestablish the lumen but perforated the inferior vena cava, which resulted in retroperitoneal abscess. In the remaining two, attempts to place the barbless stents across the tight stenosis were complicated by migration as the stents were released from the catheter. The stents formed a cone, with the distal end expanded in the normal inferior vena cava and the proximal end closed in the stenotic portion (Fig. 3). This closed, proximal end obstructed blood flow, resulting in thrombus formation.

CLINICAL APPLICATION

Case 1

Severe stridor and a superior vena cava syndrome developed in a 42-year-old woman secondary to a poorly differentiated carcinoma of the trachea involving the mediastinum that did not respond to radiation therapy. Surgical debulking was attempted to alleviate her symptoms. The distal trachea was partially resected and reconstructed with a myocutaneous graft. However, the myocutaneous graft collapsed with each inspiration, and the patient required the assistance of a positive pressure respirator to breathe. The superior vena cava syndrome persisted.

Superior cavography demonstrated stenosis of both innominate veins and the superior vena cava at their injunction. An attempt to dilate the stenosis with two angioplasty balloon (9-mm-diameter) catheters was not successful.

Four regular barbless stents, each 3 cm in diameter and 3-cm long, were placed in the right innominate vein and superior vena cava (Fig. 4). Another stent was placed into the distal trachea to prevent the collapse of the myocutaneous graft.

After stent placement, there was immediate relief of the superior vena cava syndrome, and the patient was able to breathe without assistance. Systemic chemotherapy was instituted but resulted in severe myelosuppression and sepsis. She died 3 weeks later. At autopsy, the superior vena cava was patent, and no clot formation was seen on the stents. The tracheal stent maintained the patency of the myocutaneous graft.

Case 2

An 82-year-old woman was admitted with edema of both legs and the lower abdomen. She had had a retroperitoneal leiomyosarcoma that had been treated with surgical resection and radiation therapy 8 years prior. She also had had chronic pancreatitis and retroperitoneal fibrosis that necessitated a choledochojejunostomy to relieve an obstructive jaundice 8 months before she was admitted with edema.

Inferior cavography demonstrated a marked stenosis of the vena cava at the level of L-4 with paravertebral collaterals. The pressure gradient across the

Table 2
Effect of Stents on Pressure Gradients (cm of saline)

Dog	Before Stent	After Stent	4 Months Later
	NS		
	0		

Note.—NS = not significant.

stenosis was 20 cm of saline.

Three barbless stents, each 2.5 cm in diameter and 3-cm long, were placed across the stenosis (Fig. 5). Immediately after stent placement, the pressure gradient was reduced to 10 cm of saline. However, one stent migrated and lodged in the hepatic segment of the inferior vena cava. On the next day, that stent migrated into the right ventricle, necessitating the placement of a bird's nest filter in the inferior vena cava to prevent migration of the other stents. Additional stents with a larger diameter (3 cm) were placed across the stenosis.

The edema of the legs disappeared and did not recur. The patient experienced no clinical problems related to the stent lodged in the ventricle. She died 5 months later with progressive disease in the retroperitoneum and abdomen. At autopsy, the inferior vena cava (encased by the recurrent tumor) was widely patent, maintained by the stents, and was free of clot formation. The stent in the right ventricle was covered by endocardium with no clot formation.

DISCUSSION

The results of this animal experiment l limited clinical experience should oe interpreted with caution. It appeared that in both the women and the dogs the stents had not expanded to their fullest diameters or to the original diameters of the vena cavas. However, they had allowed enough blood flow through the stenoses to decrease the pressure gradients. In case 2, the expansile force of the stent not only immediately neutralized or relieved the extrinsic compression from fibrosis or tumor on the vessel wall but also prevented progression of the stenosis.

The stents failed when they were placed in a thrombotic or occluded vessel. The presence of blood clot or intraluminal tumors may limit the use of the Gianturco stent. An intraluminal tumor will probably grow around the wires of the stent. Lysis of the blood clot by thrombolytic agents could be helpful before stent placement. Placement of the stent into a tight stenotic lesion may not adequately expand the lumen to allow sufficient blood flow, which would result in thrombosis. In such instances, balloon dilatation before stent placement should be considered.

Early migration of the stents oc- ırred in two dogs. When released om the catheters, the stents tended to spring into the nonstenotic portion of the vessel and formed a cone, the narrowed end of which obstructed blood flow and resulted in thrombosis. To avoid early migration, double stents and barbed stents were used. As the leading stent was released from the catheter, the other remained within it, which allowed slight manipulation or change in position and thus better stabilization.

The stent in case 2 most likely migrated because the size of the inferior vena cava was underestimated. As demonstrated on the radiograph of the inferior vena cava obtained before stent placement, the caval diameter above the stenosis was only 1.2 cm, compared with the diameter of 2.5 cm after placement of the stents. Thus, a 2.5-cm diameter stent was apparently too small. To prevent such migration, the selection of the proper stent diameter and use of a barbed stent are recommended for fixation of the stent to the caval wall.

The expansile force of the stent increases with an increase in the caliber of the wire, in stent diameter, and in the number and angle of wire bends. However, an increase in length will de- ·ease the expansile force. The expan- ɔile mechanism and the introduction of the Gianturo stent are much simpler than those of grafts made of nitinol wire. It spontaneously returns to its original shape after release without the changes in temperatures required in use of nitinol wire. Its expansile mechanism is also simpler than that of the Palmaz graft, which uses an angioplasty balloon to expand the graft. The ability of the Gianturco stent to expand slowly over time may also offer an advantage over the other types of stents.

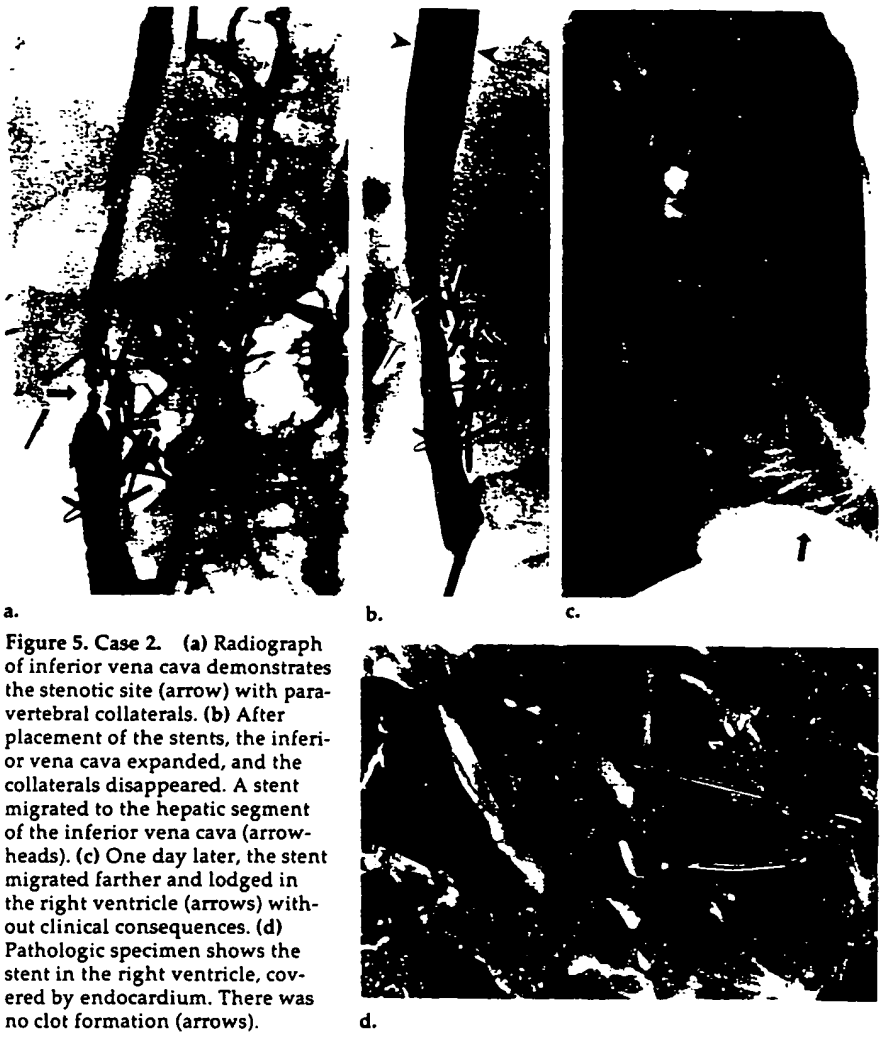


Figure 5. Case 2. (a) Radiograph of inferior vena cava demonstrates the stenotic site (arrow) with paravertebral collaterals. (b) After placement of the stents, the inferior vena cava expanded, and the collaterals disappeared. A stent migrated to the hepatic segment of the inferior vena cava (arrowheads). (c) One day later, the stent migrated farther and lodged in the right ventricle (arrows) without clinical consequences. (d) Pathologic specimen shows the stent in the right ventricle, covered by endocardium. There was no clot formation (arrows).

Conventional treatment for stenosis of the vena cava secondary to tumor encasement is radiation therapy or chemotherapy (5–8). Successful relief of superior vena cava syndrome has been reported in as high as 94% of patients. Resolution of the signs and symptoms may have a latent period up to 3 weeks (5). For stenosis from surgical or postradiation fibrosis, the treatment is more difficult. Bypass surgery or surgical correction is considered a major undertaking and may not be worth the effort, particularly in patients who still have residual or recurrent tumor (9).

Clinical application of the Gianturco stent seems appropriate for further investigation, particularly in patients with a vena cava that is stenotic because of encasement from a tumor that has not responded to radiation therapy or chemotherapy or because of postsurgical and radiation fibrosis. ■

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Tracheobronchial Tree: Expandable Metallic Stents Used in Experimental and Clinical Applications[1]

Work in Progress

An expandable stainless steel stent was formulated for use in the treatment of tracheobronchial stenosis, tracheomalacia, and airway collapse following tracheal reconstruction. The stents were placed through an endotracheal tube into the trachea and bronchi of 11 healthy dogs. The stents expanded over time, substantially increasing the diameter of the lumen. Slight migration occasionally occurred, while an inflammatory reaction was noted in each animal. The stents were successfully used in the treatment of two cancer patients to dilate a postoperative bronchial stenosis that caused pneumonia and to support a tracheal graft that collapsed with respiration. Because of the stent migration in experimental studies, designs are being tested to develop stents with greater stability. These stents may be effective in overcoming stenosis caused by scarring, extrinsic compression, and collapse of reconstructed tracheobronchial structures.

Index terms: Bronchi, stenosis, 671.741 • Trachea, diseases • Trachea, intubation, 671.456 • Trachea, stenosis

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[1] From the Departments of Diagnostic Radiology (C.C., K.O., C.H.C., K.C.W., C.G.) and Surgery (R.M., M.M.) and the John S. Dunn Summer Student Grant Program (M.J.W.), University of Texas, M.D. Anderson Hospital and Tumor Institute, Houston. Received July 23, 1985; accepted and revision requested September 4; revision received September 23. This work was supported in part by the John S. Dunn Research Foundation and the George A. Cook Memorial Fund.

NECESSITY to maintain the integrity of the airway in patients with tracheobronchial stenosis, tracheomalacia, and airway collapse following tracheal reconstruction has stimulated the search for an adequate stent (1-10). The expandable stainless steel stent for intravascular use devised by Gianturco and reported by Wright et al. seemed appropriate for further investigation in the tracheobronchial tree (11). We report our experimental studies with placement of stents in the trachea and bronchi of dogs and the initial clinical application in two patients.

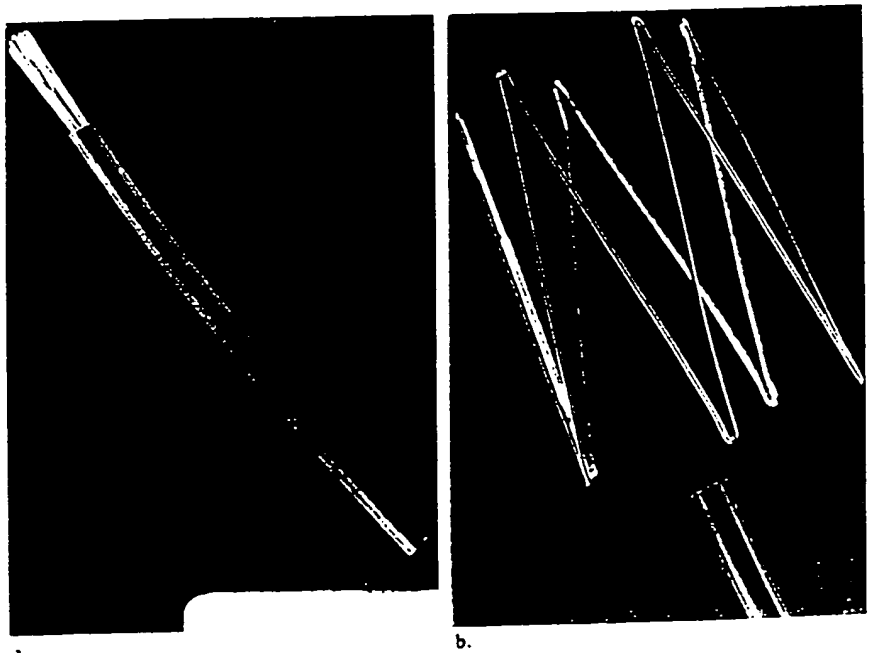
MATERIALS AND METHODS

Expandable Stent

The stents were constructed of 0.018-inch stainless steel wire formed in cylindrical zig-zag configuration of five to ten bends (Fig. 1). The relaxed diameter of the stents was 2 cm and 4 cm and their length 2.5 cm. Stents were used individually or two stents were connected by a wire strut and inserted together. With centripetal pressure, the stent was placed first in a cartridge made of 12-F Teflon tubing. The cartridge was connected to a Teflon delivery catheter of the same diameter, and the stent was pushed through the catheter into the tracheobronchial tree using a flexible cable.

Experimental Studies

An endotracheal tube was placed in the proximal trachea of eight mongrel dogs (weight, 15-25 kg) under general anesthesia. With fluoroscopic guidance, a 12-F Teflon catheter was passed through the endotracheal tube into the trachea or bronchi. The tip of the catheter was located at the site at which the stent was to be deposited. When the stent arrived at the tip of the catheter, the "pusher" catheter was held in place while the outer catheter was withdrawn, exposing the stent. As



a. b.

Figure 1. Expandable stainless steel stent. (a) Stent in a 12-F Teflon cartridge. (b) Fully expanded stent after release from the cartridge.

[illegible] stent remained partially [illegible] its position could be altered. However, once released, only slight adjustment could be accomplished.

The animals were monitored every 2 weeks by radiographic examination for changes in size and position of the stents and by clinical assessment for cough, hemoptysis, respiratory compromise, and difficulty in swallowing or eating. After 4–10 weeks of observation, the dogs were killed and the trachea, bronchi, and esophagus were examined grossly and histologically.

After the first group of eight animals was studied, stents were placed in the tracheobronchial tree of a second group of three dogs with the addition of intramuscular antibiotics (penicillin G procaine, 150,000 units/day for 4 days before and 300,000 units every other day for 3 weeks after the stent placement). These dogs were followed for 5–8 weeks, killed, and evaluated in a similar manner.

RESULTS

Radiographic Examination

In the first group of dogs, multiple stents were placed in the trachea and bronchi in all eight, in the bronchus in six, lower trachea in six, midtrachea in four, and upper trachea in 2. The stent placed in the bronchus did not migrate in five of the six animals, while in the remaining dog, the stent moved 9.5 cm up into the trachea during the last 4 weeks of the 8-week follow-up after an episode of coughing. The stents in the lower trachea migrated in five of the six animals, ranging from 2.0 cm up to 4.3 cm down the trachea and frequently straddling the bifurcation. The stents positioned in the midtrachea moved in all four dogs, from 0.7 cm up to 3.0 cm down the trachea. In the two dogs in which the stent was deposited in the upper trachea, the downward migration was 1.5 cm and 2.7 cm.

The tracheobronchial tree expanded at each site where the stent was placed. The bronchus dilated 0.7–1.3 cm, while the trachea enlarged 0.6–1.9 cm (Figs. 2, 3).

The esophagus, as studied during barium examination, exhibited slowed or impaired peristalsis and appeared more flaccid in three of the eight animals. The overexpanded segments of the trachea at the stent sites impinged on the esophagus, creating areas of relative narrowing with dilatation above.

In the second group, which received antibiotics, stent migration occurred in two of the three dogs, moving upward 1.5 cm and 3.5 cm. The trachea expanded 0.7–1.4 cm, while the bronchus dilated 0.5–0.7 cm. Only slight changes in peristalsis were noted in the esophagus in one animal.

Moderate coughing without hemoptysis was experienced by all 11 animals, but they were otherwise normal and active.

Pathologic Examination

During autopsy, the tracheobronchial tree was removed and opened on its posterior aspect. Mucosal inflammation (tracheitis and bronchi[illegible] was [illegible] at the sites of stent placement in each animal of the [illegible] group. Despite the use of procaine penicillin in the second group, the mucosal inflammation was the same. The stents that had remained in place for 4–8 weeks were partially covered by mucosal proliferation.

Multiple sections were taken alongside and beneath the arms of the stent. Microscopically, some of the sections were covered by pseudostratified, ciliated, columnar epithelium characteristic of the respira-

Figure 2. Endotracheal stent in a dog. (a) Two stents joined by a wire strut immediately after placement in the trachea. (b) Stent, 1 week later. (c) Note progressive expansion of stent 1 month later.

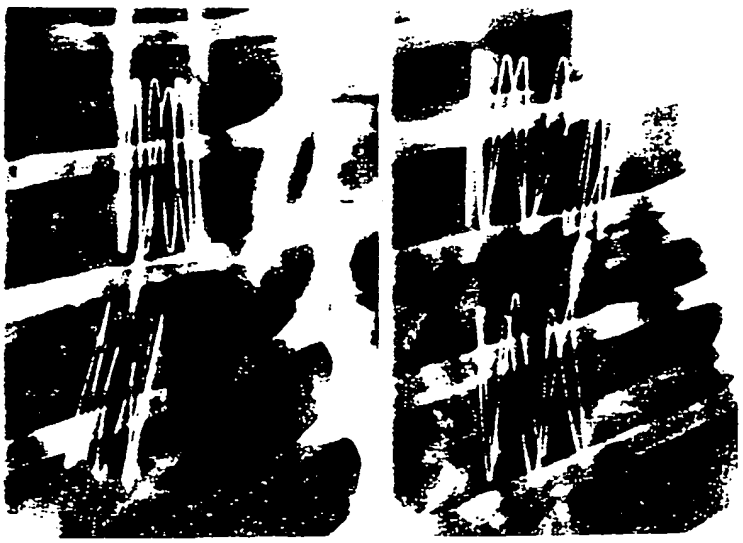


Figure 3. Combined endotracheal and endobronchial stent in a dog, immediately after placement (a) and 1 month later (b).

Figure 4. Case 1. Radiographs of man with postoperative bronchial stenosis treated with stents. (a) Pneumonia of the right middle and lower pulmonary lobes associated with stenosis of the right bronchus at the site of anastomosis. (b) Three stents were placed in the right bronchus and one in the distal trachea. (c) Note slight migration of bronchial stent 1 week later. (d) One month later, stents have remained in position. Right bronchus is dilated, and pneumonia has cleared.

filled with necrotic debris was noted, presumably caused by a strut of the stent.

Comment

The experimental data showed that it was possible to place stents in the tracheobronchial tree of dogs. At the site of the stents, the trachea and bronchi had been gradually dilated to a diameter approximately one-third greater than before stenting. In the dogs, we were not able to avoid a localized inflammatory reaction using procaine penicillin. The displacement of the stents indicated the need for better fixation.

It was also obvious that the clinical use of these intratracheal and intrabronchial devices was justified to maintain or reestablish an adequate airway. This was the case in the following two clinical reports.

CLINICAL EXPERIENCE

Case 1.—A 75-year-old man with squamous cell carcinoma of the upper lobe of the right lung was treated by a sleeve resection. The anastomosis of the right main-stem bronchus and the bronchus intermedius was complicated by a stenosis, 0.5 cm in diameter, and chronic pneumonitis beyond the obstruction (Fig. 4). Bouginage and balloon dilatation were performed with no significant improvement (12).

With the patient under general anesthesia, a bronchoscope was placed with the tip positioned above the tracheal bifurcation. With fluoroscopic guidance, a 12-F Teflon catheter was passed through the bronchoscope to the area of the stenosis. Two metallic stents, 2.5 cm in diameter and 2.5 cm in length, bridged the stenosis, and one stent, 4 cm in diameter and 2.5 cm in length, was deposited at the tracheal bifurcation.

Only one stent migrated slightly, 0.5 cm. After stent placement, there was no respiratory difficulty, such as coughing, hemoptysis, or other signs of tracheobronchial irritation. The pneumonia cleared in 1 month. The stenotic bronchus, initially 0.5 cm in diameter, gradually distended, reaching 1.5 cm in 4 months.

At bronchoscopy at monthly intervals, the bronchus was patent, and the diameter of the right bronchus eventually became 0.5 cm greater than the left. There were no inflammatory changes in the right bronchus or at the tracheal bifurcation. Slight pressure effect was noted about the stent with mucosal overgrowth.

The patient died of cerebral metastases 7 months after the stents were introduced into the bronchus. An autopsy was not performed.

Case 2.—A 42-year-old woman was admitted with severe stridor and with a superior vena cavai syndrome due to a poorly differentiated carcinoma of the distal trachea with mediastinal extension. Treatment was instituted by surgical debulking in an attempt to alleviate the patient's complaints. The distal trachea was partially resected just above the origin of the right main-stem bronchus. Reconstruction was accomplished with a myocutaneous flap. Postoperatively, the trachea collapsed at the graft site with each inspiration, necessitating the assistance of a positive pressure respirator. The superior vena caval syndrome persisted in the areas drained by the superior vena cava.

With the patient under general anesthesia and with fluoroscopic guidance, a 12-F Teflon catheter was placed through the tracheostomy tube with the tip resting just above the tracheal bifurcation and the reconstructed site. A single stent, 4 cm by 2.5 cm, was deposited at the site of the graft. The stent furnished support to this area, immediately relieved the patient of respiratory distress, and obviated the need for the respirator. In addition to the tracheal stent, stents were placed in the superior vena cava. In the following days, the swelling secondary to venous compression disappeared. After these encouraging results, the patient underwent chemotherapy but succumbed to toxicity 3 weeks later.

At postmortem examination, there was no evidence of tracheitis. The tracheal stent remained in situ, and the superior vena cava was patent.

DISCUSSION

Tracheal stenosis has resulted from vehicular accidents, prolonged tracheal intubation, extensive burns, and tumor resection. Extrinsic compression secondary to mediastinal and neck neoplasms, vascular rings, and anomalous vessels also may be responsible for tracheal stenosis (3–5). Tracheomalacia, either primary or secondary, may cause physiologic stenosis, and maneuvers such as crying, straining, and coughing increase the likelihood of tracheal collapse (7).

Tracheal resection of up to 7 cm and end-to-end anastomosis is the treatment of choice for stenotic lesions of the trachea (5). In addition, intrinsic mural or external supportive stents—composed of auricular cartilage, hyaline rib cartilage, urinary bladder graft with associated osteogenesis, plastic such as Teflon and polyethylene, and silicone rubber tubes—have been used to maintain the patency of the reconstructed trachea (3, 6, 7, 9, 10, 13, 14). The expandable metallic stent may provide an alternative method for the treatment of tracheobronchial stenosis, either as a primary treatment, in conjunction with surgical reconstruction, or when reconstruction has failed.

The stainless steel stent can be fashioned as to expansile properties, length, and diameter to suit the specific requirements. In our animal experiments, overdistention was done purposefully to demonstrate the progressive expansion caused by the stents. This progressive expansion should be effective in overcoming stenotic areas caused by scar formation, extrinsic compression of the trachea and bronchi, and collapse of the reconstructed tracheobronchial structures.

While tracheitis occurred at the stent site in all dogs, infection did not complicate the stent site in our two patients. These patients were receiving similar antibiotic coverage as part of their overall treatment. In addition, there were no symptoms or signs of tracheal irritation in the two patients. Although minimal stent migration occurred in the patients, it did not cause any clinical problems. Because the stents migrated in the dogs, we are testing stent designs that should result in greater stability of these devices. ■

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Expandable intraluminal vascular graft: A feasibility study

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An expandable intraluminal graft mounted coaxially over an angioplasty balloon catheter was used in dog arteries. The graft, a wire mesh tube that has the ability to retain its expanded shape, opposes elastic recoil of the arterial wall after maximum balloon inflation. Eighteen grafts were placed in the abdominal aorta and iliac, femoral, renal, superior mesenteric, and carotid arteries of eight dogs through femoral or carotid arteriotomies. Two grafts were placed in areas of artificially induced stenosis, completely restoring the lumen. Overall patency rate at 35 weeks was 77%. Histopathologic examination of patent grafts showed complete endothelialization at 3 weeks. The smaller caliber grafts and those that had outflow obstruction showed significant degrees of intimal hyperplasia.

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PERCUTANEOUS BALLOON DILATATION of elastic vascular stenoses tends to be ineffective if the expanded diameter of the angioplasty balloon has the same diameter as the adjacent normal vessel. The failure of the elastic recoil of the wall is due to the fibrocollagenous nature of the lesion to be dilated. This is particularly true in synthetic graft-vessel anastomotic fibrous hyperplasia[1,2] and other fibrous vascular lesions such as Takayasu's arteritis and neurofibromatosis.[3,4] In an attempt to overcome elastic recoil in lesions that are usually refractory to balloon dilatation, we have developed an expandable intraluminal graft that allows simultaneous dilatation of the stenotic lesion and prevents recoil of the arterial wall.

CONSTRUCTION OF THE GRAFT

The expandable intraluminal graft is made of continuous, stainless steel wire woven in a criss-crossed tubular pattern. Wire of 0.15 mm thickness was used for grafts 4, 5, 6, and 8 mm in diameter, and 0.20 mm wire was used to construct a 10 mm graft. The length of all grafts was 20 mm except for a single 50 mm long graft. The thickness of the graft wall did not exceed 0.45 mm for the 10 mm graft and 0.2 mm for the smaller grafts. After construction, the graft was carefully compressed to less than one third of the initial diameter, avoiding overlapping of adjacent wires, and it was mounted coaxially over a tightly folded angioplasty balloon, allowing minimal increase in diameter. The

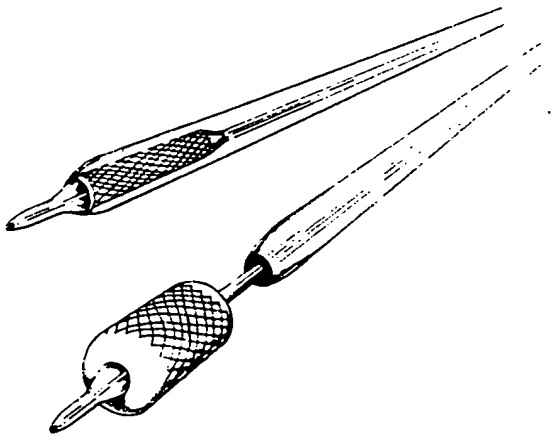

Fig. 1. Schematic drawing of the balloon-mounted graft in the collapsed and expanded states.

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Table I. Graft data

Graft diameter (mm)	*Artery location*	*Longest follow-up*	*% Luminal stenosis*
4*	Internal iliac†	7 Wk	90
5*	Renal†	3 Wk	Delayed occlusion
5*	Common femoral†	4 Wk	Delayed occlusion
5	External iliac†	30 Wk	40
5*	External iliac†	30 Min	0
6*	Superior mesenteric	5 Wk	34
6*	Carotid	3 Wk	0
6	Superior mesenteric	30 Wk	15
6*	Superior mesenteric‡	2 Hr	30
6	External iliac	31 Wk	40
6*	Renal	11 Wk	Acute occlusion with recannalization
6*	Internal iliac	5 Days	0
8	Carotid†	35 Wk	15
8*	External iliac	—	Acute occlusion
8	External iliac	30 Wk	15
8*	External iliac†	8 Wk	0
10	Infrarenal aorta†	34 Wk	30
10*	Infrarenal aorta†	17 Wk	0

*Graft removed for histopathologic examination.
†Intravenous systemic heparinization used at time of graft placement.
‡Partial thrombosis immediately after placement.

mounted graft was retained in place on the balloon catheter during manipulation by the use of leading and trailing retainers at both ends of the balloon (Fig. 1). Eight and 10 mm grafts were introduced through 12F Teflon sheaths, and 8F sheaths were used for the smaller grafts. The woven mesh allows for 20% to 30% variability in the expanded diameter, therefore the inflated balloon diameter determined the diameter of the fully expanded graft.

EXPERIMENTAL MATERIAL AND METHODS

Eighteen grafts with diameters of 4, 5, 6, 8, and 10 mm were placed in major arteries of eight 45- to 60-pound dogs under halothane anesthesia (Table I). The graft diameter was chosen from the five available sizes to match the angiographic diameter of the target vessel after correction for magnification. The balloon-catheter assembly was introduced through femoral or carotid arteriotomies that were repaired after the procedure (Fig. 2). The first nine grafts were installed without the use of heparin. Systemic heparinization (50 U/kg) was used immediately before the introduction of the other nine grafts. No long-term anticoagulation or antiplatelet medication was used.

Serial arteriography was performed before and after graft introduction and at 2-week intervals for as long as 18 weeks. Thereafter arteriography was repeated at monthly intervals. Twelve of the 18 grafts were removed with adjacent artery segments for histologic examination at intervals that ranged from 30 minutes to 17 weeks (Table I). The remaining six grafts are being followed for an extended period of time. The fact that we removed only one graft at each time interval determined that each histopathologic observation was done only once for a graft of any given age. Undoubtedly, more solid data could have resulted from fewer study intervals on the same number of grafts. Nevertheless, because this was a preliminary study, we used the largest possible number of observations in an attempt to better understand the chronology of the graft healing process. Hematoxylin-eosin, trichrome, and elastin stains and transmission and scanning electron microscopy were performed on the specimens.

Decrease of the graft's lumen by thrombus or neointimal hyperplasia was assessed on arteriograms by subtracting the diameter of the opacified lumen from the diameter of the radiopaque wire graft. Because the graft is rigid, no change occurred in lumen diameter when intraluminal pressure was removed. Therefore the thickness of the material interposed between graft and lumen was the same when measured directly on the fresh specimen or on the arteriogram after correction for magnification.

A preliminary study was done to investigate the

Fig. 2. A, Collapsed catheter-graft assembly before inflation in the lower left common carotid artery of a dog. B, Follow-up arteriogram of the grafted site 17 weeks after placement.

ability of the grafts to oppose elastic recoil. Rubber bands were tied around surgically exposed infrarenal abdominal aortas of two dogs. A 10 by 20 mm graft and a 10 by 50 mm graft were then introduced across the obstruction and expanded to achieve complete restoration of the lumen.

RESULTS

Four grafts (two 5, one 6, and one 8 mm in diameter) became occluded during the first 7 weeks. The patency rate remained unmodified thereafter for as long as 35 weeks (Fig. 3). Two of the graft occlusions occurred immediately after placement (Table I). One occurred in a renal artery that became kinked because of an excessively long graft causing decreased flow. Nevertheless it was found to be recannalized 2 weeks later. The second acute thrombosis occurred in an iliac graft as a result of decreased blood flow caused by a faulty arteriotomy repair in the ipsilateral femoral artery.

Outflow restriction was recognized at the time of placement in the two delayed occlusions. Severe renal artery branch spasm caused by excessive catheter manipulation caused thrombosis of a renal graft, and

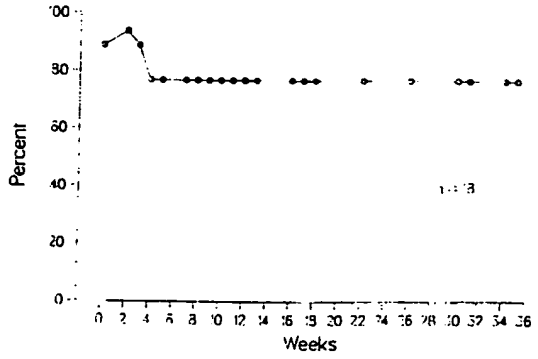

Fig. 3. Graph shows overall patency with time. The upgoing portion of the curve reflects the single case of recanalization after initial thrombosis.

an inadequate arteriotomy repair thrombosed an ipsilateral femoral graft. All of the grafts that thrombosed were placed in nonheparinized dogs. No evidence of thrombosis was found among grafts placed in systemically heparinized animals.

Allowing for the small number of observations, the degree of intimal hyperplasia restricting the graft

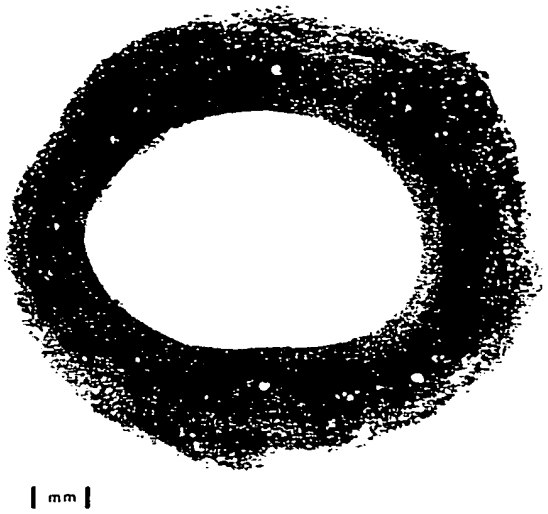

Fig. 4. Transverse section of a 6 mm iliac artery graft 12 weeks after placement. A moderate amount of intimal hyperplasia covers the graft.

lumen was inversely proportional to the transverse diameter of the graft (Fig. 4). In general, the grafts that had low-grade intimal thickening were deployed without restriction of the outflow vessel, such as the carotid artery grafts introduced through femoral arteriotomy and the iliac artery grafts introduced through carotid arteriotomy.

The two aortic grafts that were placed across obstructions caused by external placement of rubber bands remained completely expanded with the bands in place. The aortic branches arising within the grafted area remained patent on follow-up arteriography and direct inspection.

Examination of the inner surface of the graft removed at 30 minutes and 2 hours after placement showed concentric lining of red thrombus over the graft. The graft examined at 5 days had a thin layer of fibrin coating the mesh wire and inner surface of the artery (Fig. 5). At 3 weeks the mesh wire could be seen through a translucent, glistening lining, continuous with the inner surface of the adjacent artery. At 8 weeks the mesh was uniformly covered by a smooth, whitish, opalescent layer.

Light microscopy studies of the specimens obtained at 5 days demonstrated a layer of fibrin with early organization covering the luminal surface of the graft. The media of the artery showed pressure necrosis and loss of elastic lamellae adjacent to the wires. Inflammatory infiltration was present in the adventitia. At 3 weeks a completely endothelialized neointima covered

Fig. 5. Longitudinal sections of grafted arteries removed at 5 days *(top)* 3 weeks *(middle)* and 8 weeks *(bottom)*

the graft. Neovascularity was present around the wires of the mesh. The media was partially replaced by fibrocollagenous tissue and the adventitia had less inflammatory infiltrate. From 8 to 17 weeks the neointima showed further organization and the neovascularity surrounding the wires was less prominent. The media was further replaced by fibrotic tissue and the adventitia had even fewer inflammatory changes (Fig. 6). The lumen of the grafts that had delayed occlusion was occupied by intimal hyperplasia.

Transmission electron microscopy demonstrated endothelial lining with tight junctions as early as 3 weeks. Scanning electron microscopy of the intimal surface at 3 weeks showed complete endothelial cover with orderly orientation of the cells in the direction of flow (Fig. 7).

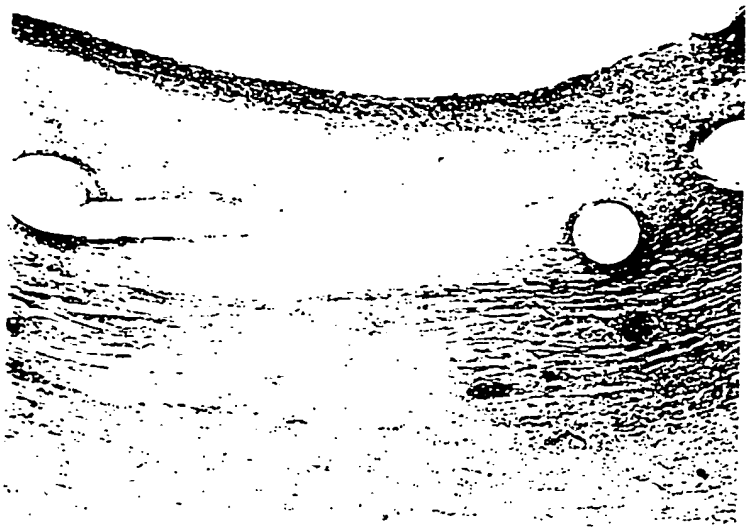

Fig. 6. Transverse section of a graft 12 weeks after placement. (Hematoxylin-eosin stain; original magnification ×100.) The empty spaces correspond to the mesh wires. The luminal side of the graft is covered with endothelialized neointima.

DISCUSSION

Intraluminal grafting of vessels was first used experimentally by Dotter[5] in 1969. His graft, made of coiled stainless steel wire, was introduced in the femoral artery of dogs, mounted coaxially over a guide wire and positioned with a pusher catheter. This early device and the ones that followed[6-9] also consisted of tubes formed by coiled wire. More recently a spring-loaded arterial stent consisting of stainless steel wire in a zigzag pattern was described by Wright et al.[10] All these grafts were designed to be placed in a location remote from the site of introduction and positioned with the aid of fluoroscopy. Since the grafts must be introduced through peripheral vessels in a collapsed form, the ability to expand after deployment is based on a spring action[9,10] or a heat-sensitive memory of the metal.[6-8] Unfortunately, the size of these grafts in the final or expanded state is predetermined and cannot be changed after deployment. In case of miscalculation of the diameter of the targeted vessel, an undersized graft might migrate while an excessively large graft might rupture the vessel. By contrast, the balloon-mounted expandable graft allows controlled dilatation of the stenotic area and, at the same time, controlled expansion of the graft. The ability of the graft to oppose recoil after expansion is because the cross points of the woven mesh are soldered. Since the expanded graft opposes elastic recoil, no need exists to prolong the balloon inflation after reaching the desired degree of expansion. This is an important feature of the balloon-mounted expandable graft because the extent of endothelial denudation during transluminal angioplasty is proportional to the balloon inflation time.[11] In theory, the amount of preserved endothelium should be large because in the expanded state 80% of the graft wall is open surface. Intact patches of endothelium between the mesh wires may result in a rapid, multicentric endothelialization pattern as shown by studies of the grafts demonstrating complete endothelial cover at 3 weeks. This is in contrast to endothelialization of other synthetic grafts in dog arteries that take several months to complete.[12] Side branches arising at the level of the graft were patent on angiography and confirmed histologically. Considering the large proportion of open surface area in the graft, these findings are not unexpected.

The thromboses that occurred among the first nine grafts motivated the use of systemic heparinization in the last nine graft placements. Nonetheless, delayed occlusion resulted among those grafts that had poor outflow. From these experiments, it is clear that heparin does not prevent occlusion of grafts with low flow and that best results were obtained in those without flow restriction.

Despite the small sample size, correlation between the degree of intimal thickening and the graft diameter was good (Fig. 3). As with other synthetic grafts, the smaller expandable grafts exhibited the largest degree

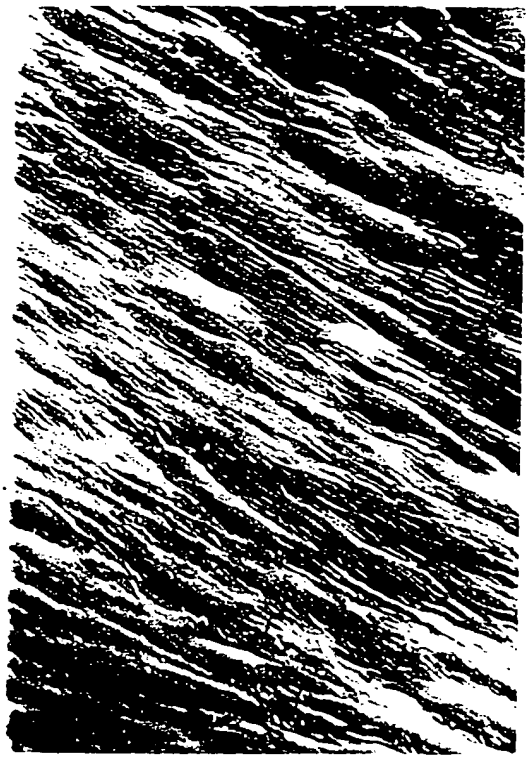

Fig. 7. Scanning electron microscopic view of the inner surface of a 3-week graft lined by endothelial cells arranged in the direction of flow (Original magnification ×1400.)

of luminal narrowing. Those grafts that exhibited marked intimal hyperplasia had a reduction of the outflow of the graft caused by vessel kinking or inadequate arteriotomy repair. In most cases the outflow reduction was recognized before the hyperplasia occurred, suggesting that the latter may be the result rather than the cause of the flow restriction. Those grafts with minimal degrees of hyperplasia had no compromise of the outflow. This agrees with observations of other investigators who have shown that low blood flow in vein grafts enhances intimal hyperplasia.[13-15]

One disadvantage inherent in this graft configuration is the lack of longitudinal flexibility, which limits its use to straight vascular segments or in curved vessels requires short graft lengths. In two of our experiments an excessively long graft caused kinking and partial thrombosis. Another potential problem is the lack of radial compliance in the graft. This could result in compliance mismatch at the transition zone with adjacent vessel inducing neointimal proliferation. Nevertheless, intimal hyperplasia did not occur at the graft ends. Instead, even those grafts with marked degrees of luminal narrowing had diffuse intimal thickening when examined histopathologically.

More meaningful data regarding graft patency could have been obtained if all grafts were placed in the same artery after introduction from a site far removed from that artery. However, our objective was to evaluate the potential of coaxial grafting by trying several graft sizes in different arteries. We focused our main interest on small-caliber grafts, from which we had rather poor results. We have solved some of the problems of graft rigidity by replacing the woven mesh with a lath design obtained by electromechanical etching of thin-walled stainless steel tubing. This results in a more delicate mesh with very low profile and uniform collapsed dimensions, more appropriate for small vessel use. Further research is currently underway with this new material.

At the time of publication the six remaining grafts have been patent for periods ranging from 15 to 18 months. No change in their luminal diameter was observed in the follow-up arteriograms.

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Injertos distensibles

En arterias caninas se utilizaron injertos intravasculares distensibles montados en forma coaxial sobre un catéter de angioplastia. El injerto, formado por un tubo de malla de alambre, que tiene la posibilidad de retener su forma distendida, se opone al retorno de la arteria elástica después de haber realizado la inflación máxima del globo del catéter. Se colocaron 18 injertos en las arterias aorta-abdominal, iliaca, femoral, renal, mesentérica superior, y carótida de 8 perros. Para realizar la implantación se utilizaron arteriotomías carotídeas o femorales. Se colocaron 2 injertos en zonas de estenosis producida artificialmente restableciendo totalmente la luz del vaso. A las 35 semanas el porcentaje global de permeabilidad de los injertos fue de 77%. El examen histopatológico de los injertos permeables mostraron endotelización a las 3 semanas. Los injertos de menos calibre y aquellos que tuvieron obstrucción al flujo de salida, mostraron grados significativos de hiperplasia de la íntima.

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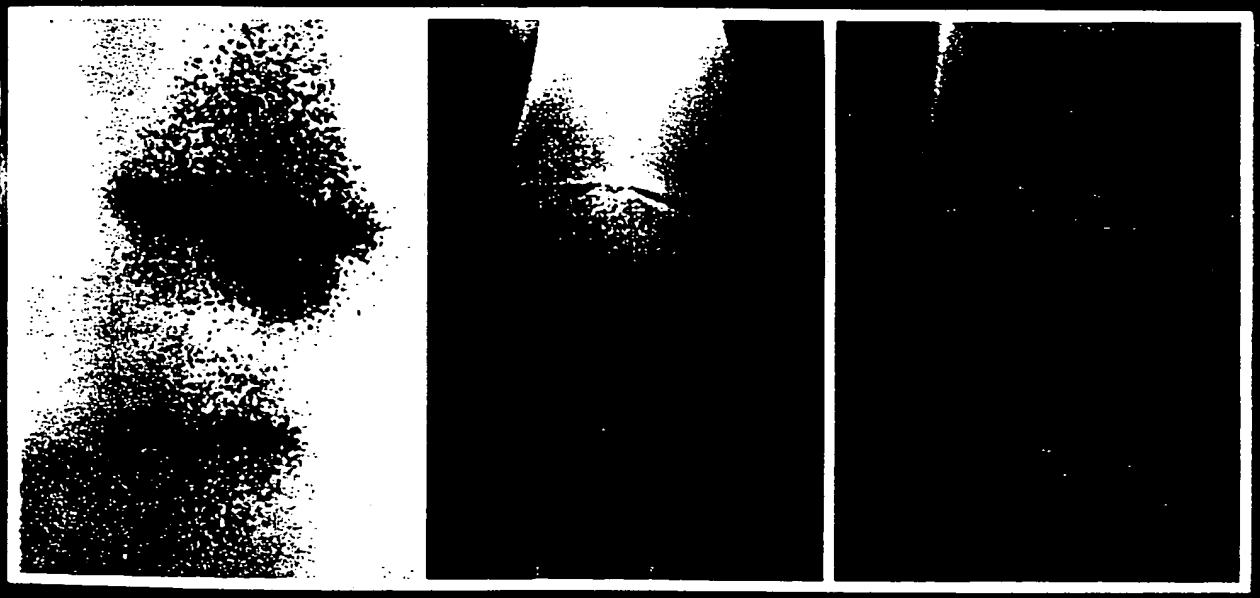

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THE RADIOLOGICAL SOCIETY OF NORTH AMERICA

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Expandable Intraluminal Graft: A Preliminary Study

Work in Progress [1]

To overcome the problem of recurrence of stenosis after vascular balloon dilatations, we developed an expandable, intraluminal graft that allows dilatation of the lesion and simultaneous placement of a supportive endoprosthesis to prevent recoil of the arterial wall. The graft is made of continuous, woven, stainless steel wire. The resulting tubular mesh has a wall thickness of 200-450 μm and 80% open surface. The grafts, mounted on angioplasty catheters, are introduced through 8-12-F Teflon sheaths. Eleven grafts of 6, 8, and 10 mm in diameter by 20 mm long were placed in the aorta, common carotid, superior mesenteric, iliac, and renal arteries of dogs. Six grafts showed no stenosis in follow-up studies of up to 8 weeks. Two grafts had moderate stenosis as a result of neointimal hyperplasia. Two partial and one complete graft thrombosis occurred in nonheparinized animals in which the graft outflow was restricted. Anticoagulant was not used on a long-term basis. Light and electron microscopy studies showed complete covering of the graft's inner surface by endothelium at 3 weeks.

Index terms: Aorta, grafts and prostheses, 56.45 • Aorta, stenosis, 56.83 • Aorta, transluminal angioplasty, 56.129 • Carotid arteries, transluminal angioplasty, 56.129

Radiology 1985; 156:73-77

MANY percutaneous, transluminal angioplasties fail because of elastic recoil of the stenotic lesion. This is usually due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilatation because the dilating forces are applied to the aortic wall rather than to the renal artery itself (1). Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters (2). Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures (3) and postendarterectomy recurrent stenoses (4). Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence, probably because of the fibrotic nature of these lesions (5).

To overcome the problem of recurrence of stenoses in these types of patients, we designed an expandable intraluminal graft that allows simultaneous dilatation of the stenotic lesion and placement of a supportive endoprosthesis that prevents recoil of the arterial wall. The endoprosthesis, a tubular wire mesh, is mounted on a modified angioplasty catheter. When the angioplasty balloon is dilated in the stenosed vessel, the wire mesh expands with the balloon and remains expanded and in place after the balloon is deflated and withdrawn.

MATERIALS AND METHODS

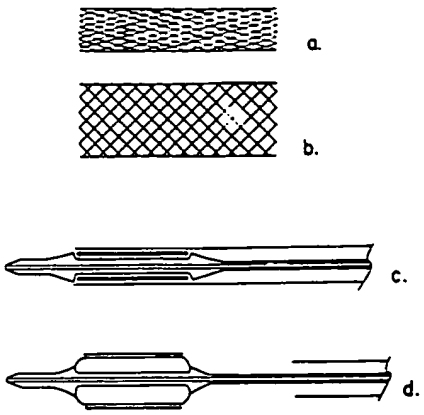
The expandable, intraluminal graft is made of continuous, woven, stainless steel wire. Wire of 150 μm in diameter is used for the 6- and 8-mm grafts, and 200-μm wire is used to construct the 10-mm graft. The cross points of the wire mesh are soldered with silver to give the tube a relatively high resistance to radial collapse and capacity to retain the diameter attained by the maximal balloon inflation. The thickness of the cross points is only slightly larger than twice the wire diameter so that the total graft wall thickness does not exceed 200 μm for the 6- and 8-mm grafts and 450 μm for the 10-mm graft. Care is taken to avoid overlapping the wire segments during the process of compressing the tube down to a diameter small enough to fit snugly around a collapsed angioplasty balloon. This allows only minimal increase over the diameter of the folded balloon. The mounted graft is retained in place around the balloon by oversize, tapered, leading and trailing retainers (Fig. 1). The assembly is introduced in the vessel lumen through an 8-F teflon sheath for the 6-mm graft and through a 12-F sheath for the 8- and 10-mm grafts.

Eleven grafts of 6, 8, and 10 mm in diameter were expanded in major arteries of six 20–27 kg dogs that had been placed under general gaseous anesthesia (Table 1). The length of each graft was 20 mm. Although the device could be used percutaneously, it was introduced through femoral or carotid arteriotomies that were sutured afterward because dogs tend to get delayed hematomas at the puncture site. The introduction of three grafts (grafts 7, 10, and 11) was preceded by the intravenous administration of 50 mg per kilogram body weight of heparin (Fig. 2). All other grafts were

[1] From the Departments of Radiology (J.C.P., R.R.S., S.R.R.) and Pathology (F.O.T.), University of Texas Health Science Center at San Antonio and Memorial Medical Center (W.J.R.), Corpus Christi, Texas. Presented at the 70th Scientific Assembly and Annual Meeting of the Radiological Society of North America, Washington, D.C., November 25-30, 1984. Received August 31, 1984; accepted November 16.

See also the article by Wright et al. (pp. 69-72) in this issue.

Figure 1



Schematic profile of the graft in the collapsed (a) and expanded (b) state. The mounted graft is protected from being dislodged out of the balloon by oversize leading and trailing retainers (c). Balloon inflation expands the graft to the maximal size attained by the balloon (d).

implanted without anticoagulants so that the thrombogenicity of the device could be evaluated (Fig. 3). No anticoagulants or antiplatelet agents were administered to the animals after graft placement so that we could determine the host response to the grafts, particularly the degree of neointimal hyperplasia.

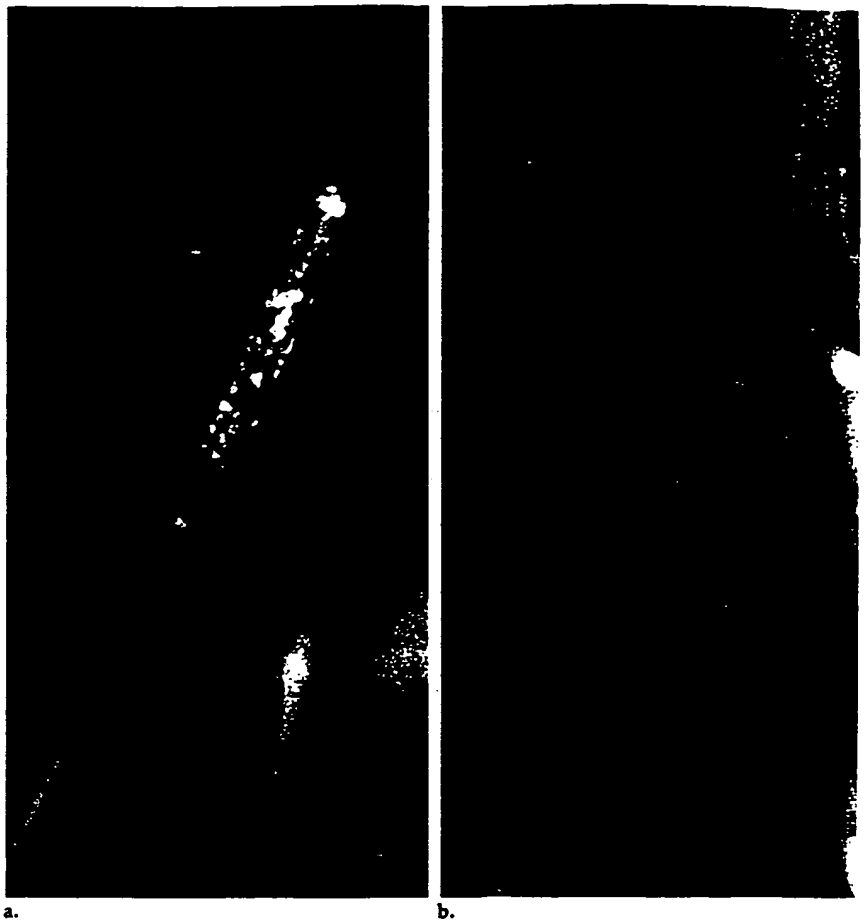
To test the ability of the system to expand stenoses with marked elastic recoil, a rubber band was tied around a surgically exposed infrarenal abdominal aorta of a dog (graft 11, Fig. 4). A 10-mm graft was then introduced across the occlusion and expanded to achieve complete restoration of the lumen.

Serial angiography was performed in each dog before and after introduction of the grafts and at 2-week intervals thereafter. Pressure recordings were obtained whenever a significant stenosis was detected with angiography. Four grafts with the adjacent artery segments were removed for histologic examination at 2 hours, 5 days, 3 weeks, and 8 weeks after placement. Transmission and scanning electron microscopy studies were performed on the specimens, which had been stained with hemotoxylin, trichrome, and elastin (Figs. 5, 6).

RESULTS

Of the 11 grafts implanted, six showed no luminal stenosis on arteriograms taken between 1 and 8.5 weeks (Table 1). Two grafts, one in the abdominal aorta (graft 11) and the other in the left carotid artery (graft 7), had moderate, delayed stenosis caused by neointimal proliferation. However, no pressure gradients were present across the stenoses. The 10-mm aortic graft (graft 11, Fig. 4) effectively opposed the recoil of the elastic band placed around the infrarenal aorta, achieving complete restoration of the luminal diameter. Follow-up angiograms showed slight reduction of the lumen at 8 weeks with no pressure gradient across the grafted area. The lumbar arteries arising at the level of the graft remained unobstructed during that same period of time.

Figure 2

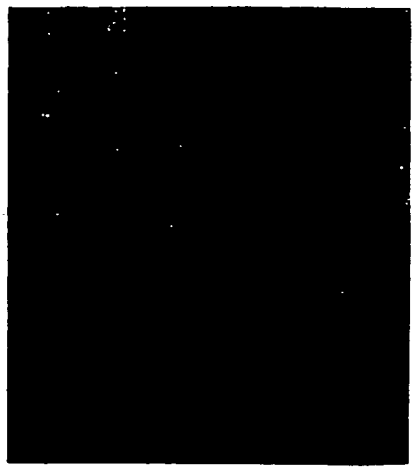


a. A collapsed 8-mm graft before expansion in the right iliac artery of a dog.
b. Aortogram taken immediately after placement of the graft.

Acute partial thrombosis was observed in two dogs (grafts 3 and 5). In both cases, reduction of the lumen resulted from kinking and spasm at the distal end of the graft because the graft was too long for the artery in which it was expanded. Acute complete thrombosis occurred after placement of an iliac graft (graft 8) in which the ipsilateral femoral artery had to be ligated after graft introduction, causing occlusion of the outflow from the graft. No anticoagulants were used in any of the dogs with acute thrombosis. Follow-up angiography of the partially thrombosed renal graft (graft 5) showed complete recanalization at 2 weeks.

Gross inspection of the graft removed 2 hours after placement showed concentric lining of red thrombus on the endoluminal surface of the graft without significant luminal narrowing. The graft removed

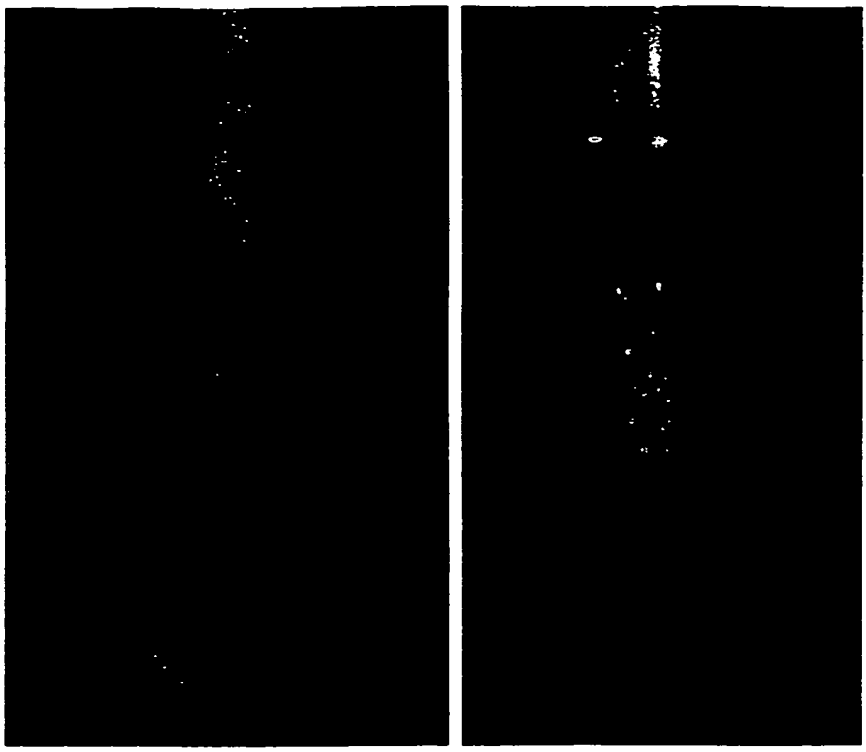
Figure 3



Proximal superior mesenteric arterial graft 4 weeks after placement.

5 days after placement exhibited a thin, fibrinous layer evenly coating the wire mesh and inner surface of the artery (Fig. 7). At 3 weeks, the wire mesh could be seen through a translucent, glistening lining that was grossly similar to the inner surface of the adjacent artery. At 8 weeks, the mesh was uniformly covered by a

Figure 4



a. b.

Experimental elastic occlusion. A rubber band has been tied around the infrarenal aorta. Complete occlusion of the aortic flow is seen in the aortogram (a). A 10-mm graft has expanded the rubber band at the occlusion, restoring flow (b). The opaque rubber band could be seen in position on original films.

Table 1
Summary of Grafts Placed in Six Dogs

No.	Graft Size (mm)	Location	Follow-up	Stenosis at Follow-up (%)
1	6	Left carotid	4 wks	0
2	6	Superior mesenteric	4 wks	0
3	6	Superior mesenteric	2 hrs	30
4	6	Left iliac	4 wks	0
5	6	Right renal*	2 wks	20
6	6	Right internal iliac	5 days	0
7	6	Left carotid	9 wks	98
8	6	Right external iliac†	1.5 wks	100
9	8	Right external iliac	2 wks	0
10	8	Right external iliac	8.5 wks	0
11	10	Infrarenal aorta	8 wks	0

*Partial thrombosis immediately after implantation.
†Complete thrombosis immediately after implantation.

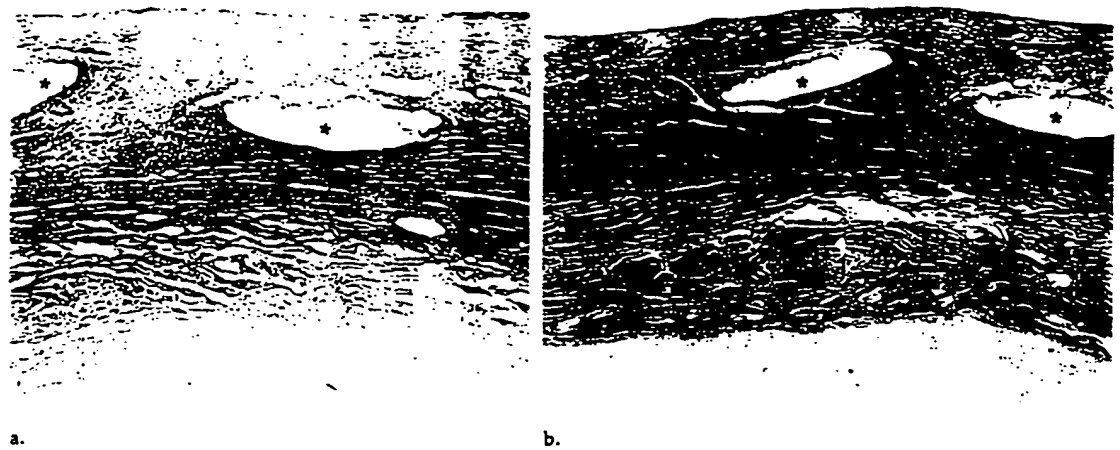
smooth, whitish, opaque layer. Light microscopy studies of specimens removed at 5 days revealed a thin, even layer of fibrin on the luminal surface with evidence of early stages of organization. The media of the artery showed evidence of pressure necrosis and loss of elastic lamellae adjacent to the wires. Inflammatory infiltration was evident in the adventitial layer. At 3 weeks (Fig. 5a), the adventitial inflammatory infiltrate had decreased and was being replaced by progressive fibrosis. The media showed replacement by fibrocollagenous tissue. The intima showed neovascularization and the development of a complete endothelial lining. At 8 weeks (Fig. 5c), the neointima showed further organization and the media had more fibrotic replacement, while the adventitia had even fewer inflammatory changes. Transmission electron microscopy was used to demonstrate a well-developed endothelial lining with tight junctions as early as 3 weeks. At 8 weeks, the endothelial surface under scanning electron microscopy appeared smoothly continuous with that of the adjacent vessel and had orderly orientation in the direction of flow (Fig. 6).

DISCUSSION

The principle of introducing intraarterial grafts percutaneously was first described by Dotter in 1969 (6). Dotter's device was a stainless steel coil tube that was introduced coaxially over a guide wire and positioned with a pusher catheter. Since the pre- and postimplantation graft dimensions were the same, the diameter was limited by the access vessel and the arteriotomy size. Nevertheless, a 2½-year patency was observed in a canine femoral graft 3.5 mm in outer diameter. As originally pointed out by Dotter (6), the potential benefits of transluminal grafting are promising. Surgical manipulation of the affected vessel—with such inherent complications as infection, perigraft hematoma, pseudoaneurysm and anastomotic strictures—can be avoided. Dotter also recognized the advantages of a permeable graft structure, which allows tissue growth through the interstices and incorporation of the graft into the vessel wall. More recently, variants of the original technique using an alloy with thermal-shape memory have been reported (7–9). The principle is based on coil springs that regain their shape intraluminally after introduction through the catheter. Cragg et al. (9) have shown successful restoration of the lumen in an experimental aortic aneurysm using a nitinol coil-spring graft. A similar technique was introduced by Maass et al. utilizing spring-loaded steel coils (10). To date, none of the experimental endoprostheses has been tested in an experimental vascular stenosis. Within the scope of a limited, preliminary study, our results are promising. Our investigation was carried out in dogs since it has been shown that, among available experimental animals, dogs approximate human graft healing most closely (11).

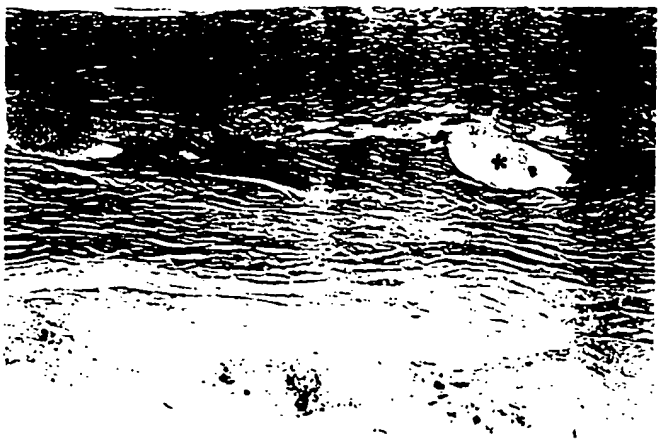
A unique feature of the expandable mesh tube is its ability to dilate an area of stenosis while being implanted; therefore, the amount of time required to implant an expandable graft is similar to that required for regular balloon angioplasty. After maximal inflation, the balloon can immediately be deflated because the mesh opposes elastic recoil. Since the extent of endothelial destruction seems to be a function of balloon inflation time (12), the vessel endothelium would largely be spared because 80% of the expandable graft is open surface. The surprisingly rapid covering by endothelium of our wire-mesh graft is probably due to intact patches of endothelium left between the wire segments that proliferate and bridge over the mesh. This finding is in con-

Figure 5



a.

b.



c.

a. Longitudinal section of the grafted arterial wall 3 weeks after placement, H and E stain, ×80. The graft is covered by a fibromuscular, neointimal layer, 200 μm thick, with evidence of neovascularity adjacent to the wires (asterisks indicate the spaces occupied by mesh wire). The endothelial surface is smooth.

b. Longitudinal section of a grafted arterial wall 3 weeks after placement, elastine stain, ×68. The elastic lamellas of the media are interrupted in the vicinity of the wires (arrows).

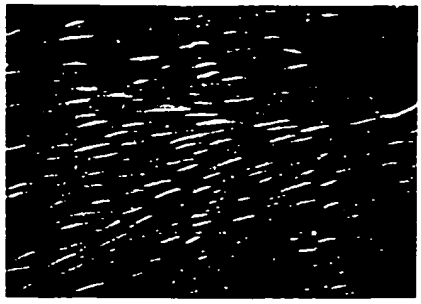
c. Longitudinal section of a grafted artery 8 weeks after placement, H and E stain, ×80. An increased amount of collagen is seen in the neointimal layer 330 μm thick. Smooth muscle and elastic tissue have disappeared from the media.

trast with covering by endothelium of synthetic grafts in dogs, which takes about 5 months to be completed (13). The inner surface of healed synthetic grafts in humans is covered by fibrin and does not become covered by endothelium (14).

Patency of side branches arising at the level of the graft was observed on angiograms and was confirmed histologically. Considering the large proportion of open surface in the graft, these findings are not unexpected. However, this attribute of the wire-mesh graft is a potential advantage over tightly wound coil-spring or solid grafts.

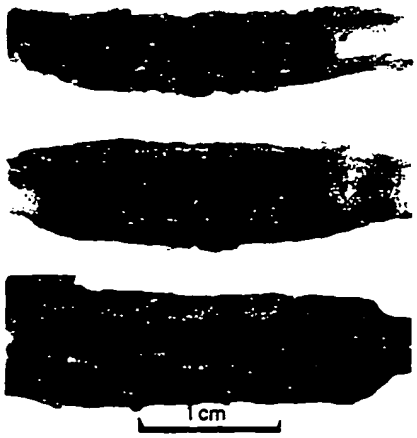
One disadvantage inherent in this graft configuration is the lack of longitudinal flexibility, which limits its use to straight arterial segments or, in the case of curved arteries, requires the use of short graft lengths. In two of our experiments (grafts 3 and 5), an excessively long graft caused kinking and immediate thrombosis. This problem was later solved by using shorter grafts or grafts in tandem. Another potential problem is that excessive radial compliance mismatch at the point of transition between artery and graft may cause sheer stress and neointimal proliferation. Nevertheless, we have not observed this occurrence in our dogs up to 8½ weeks following the procedure. In fact, electron microscopic studies at the area of transition showed no endothelial alteration, nor was any prominent myointimal proliferation present on light microscopy.

Figure 6



Scanning electron micrograph (×480) of the luminal surface of the midportion of a graft 8 weeks after placement. A regular endothelial lining is present, and the cells are oriented in the direction of blood flow.

Figure 7



Longitudinal section of an internal iliac graft, 5 days after placement, shows a concentric layer of fibrin clot with a rough, granular, luminal surface (top). Similar section of a carotid graft at 3 weeks shows the wire mesh through a translucent layer of neointima (middle). Longitudinal section of an iliac graft demonstrates an opalescent, smooth layer of neointima throughout the inner surface of the graft (bottom).

Balloon dilatation of atherosclerotic lesions results in splitting and shearing off of plaque elements (15). The magnitude of embolization of de-

tached fragments and clumps of cells seems to be relatively unimportant, as indicated by the low frequency of distal embolization in iliac and femoral angioplasties (16, 17). However, if large amounts of thrombotic material are mobilized during dilatation, as occurs in recanalization of totally occluded iliac arteries, distal embolization is often observed (18). Cerebrovascular embolization is also a major obstacle to the performance of percutaneous dilatation of carotid stenosis, attested to by the relatively few reported cases (19). Theoretically, the expandable graft could restore patency while avoiding downstream embolization by supporting fractured plaque elements. Further research in this area is warranted. As with other intraluminal grafts, the expandable mesh tube could be applied to restore patency in other organic tubular structures that are currently subjected to balloon dilatation, such as bile ducts, ureters, and bronchi.

Investigation of grafts of smaller size is currently being carried out, especially in vessels in the range of 3–4 mm in diameter. We have used expandable grafts within the liver parenchyma of dogs with portal hypertension to create portocaval shunts. The preliminary results are encouraging, but further investigation is necessary. ■

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Percutaneous vascular stent: Experimental studies and preliminary clinical results in peripheral arterial diseases

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SUMMARY.—A new pattern of metallic intravascular stent has been experimentally and clinically tested. When the stent is percutaneously placed through a six french introducer, it is held against the vessel wall by its natural elastic properties. In 28 animals, 47 stents of different sizes (from 3 to 5 mm of ∅ and from 1.5 to 5 cm of length) have been implanted in the femoro-popliteal (16), the coronary (20), the carotid (3) and the renal arteries (5) and in 3 femoral veins. Angiographic and histological results have shown the stent's low thrombogenicity when it is well fit to the vessel's caliber. Moreover, they have shown its incorporation to the vessel wall by intimalisation as early as the third week after its implantation. The collateral vessels which covered by the stent remain permeable. At the end of this experimentation, 10 implants have been achieved in 8 patients (4 recurrences of iliac stenosis and 6 femoral stenosis). The angiographic results show the perfect tolerance of the organism at 6 months. This good tolerance is revealed by a thin intraluminal border which does not change the artery's diameter. This confirms the experimental results. The permeability is good except for two patients who had an obliteration after one month (one iliac and one femoral obliteration).

KEY WORDS.—Arteries - Transluminal angioplasty - Artery prosthesis - Vein prosthesis.

INTRODUCTION

Percutaneous angioplasty is highly efficient but it has its limitation particularly recurrences which are more frequent after the coronary and femoral transluminal angioplasty.

In order to supply to this drawback, the solution of an intravascular stent seems attractive. The stent must allow a new permeability of an atherogenous stenosis, and must prevent restenosis for a long term. In 1969, Dotter published the first transluminal implantation of a metallic spring in a dog's popliteal artery, since then, some teams have studied with various success the placement of different types of stents.

We report our experience about 47 percutaneous animal implantations of a metallic stent. This stent's originality relies on its natural elastic properties. We also report preliminary results of human implantation[4] in iliac and superficial femoral arteries.[2]

MATERIALS AND METHOD

The intravascular metallic stent designed by the Medinvent Company is composed of wire netting stainless steel alloy multifilaments which are not attached. The stent strechly placed, spontaneously regains its expansion by applying to the vascular wall as soon as it is released (see Fig. 1). Different sizes of the stent have been used. In all cases, the introducer's diameter is a 6 F caliber.

The multifilament which formed the stent have a diameter varying from 0.07 mm to 0.1 mm

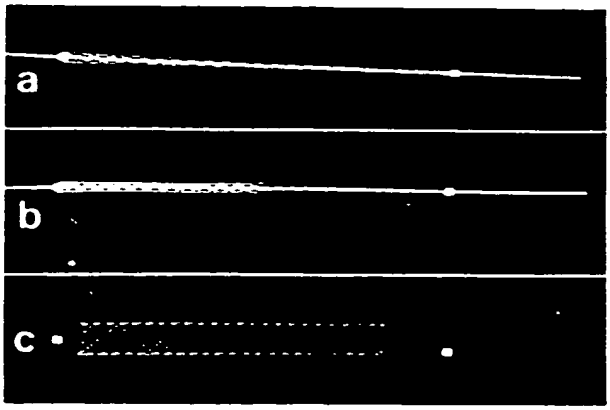

Fig. 1.—(A) The prosthesis elastically streched longitudinally and constrained to a small diameter on its delivery device. (B) Controllable progressive deployment of the device from the instrument permits expansion of the prosthesis and fixation of it against the internal vascular wall. (C) Inside the catheter we can place a 0.35 mm movable guide wire.

The pressure applied to the vascular wall can be measured before the implant. This pressure depends on two parameters:

— the multifilaments' diameter;

— the ratio between the stent's diameter and the vascular lumen's diameter.

When the ratio increases, the pressure applied to the vascular wall proportionality increases.

While the stent is placed, it is strechly set up on a central catheter. A movable guide of 0,35 mm of ∅ (or 0.014 inch of ∅) can go through this central catheter.

The catheter as well as the stent are covered by an outer tube which can be distended by an inflator, like an angioplasty balloon.

Once the tube is distended, it can be progressively pulled out. So doing, the stent is released and it spontaneously applies to the vascular wall thanks to its elasticity.

Experimental study

This work had two objectives:

— to improve the stent's physical properties starting from the first basic suggested pattern, so as to lay down the rules of the stent's choice in relation to the vascular's caliber;

— to evaluate the stent's vascular tolerance particularly the thrombogenicity and the adaptability to the vascular wall.

Forty-seven stents from 3 to 6 mm of ∅ from 1.5 to 5 cm of length have been implanted in most arteries: iliac, femoral axillary (16), renal (5), carotid (3) and coronary arteries (20) and in 3 veins of 28 animals (ten sheeps and eighteen dogs).

The femoral artery puncture is done under general anesthesia (sodic thiopental 20 mg per kg), either percutaneously or by denudation to prevent local hematoma in dogs.

The stent's placement is done after selective catheterism of the chosen artery to implant and after opacification to evaluate its diameter.

Two methods have been used:

— the stent is introduced in the coronary arteries by the coaxial technique with the help of a coronarography carrier;

— a 0.36 mm guide is left in the other arteries after selective catheterism.

This guide allows the introduction of the stent's catheter to the desired place.

Different sites of implantation have been chosen:

— accross the collateral branches in order to evaluate the stent's thrombogenous effect on them;

— at vascular curves on purpose to evaluate the stent's thrombogenicity and tolerance at these places.

Neither anticoagulant nor anti-agregating agents have been used before or after the implantations. This is to objectify the real stent's thrombogenicity and the local tissular reaction of new intimalisation.

Angiographic controls have been done at different moment few hours after the implantation to 6 months later, according to the case.

Macroscopic and microscopic histological analysis have been performed after the angiographic study.

The standard optical microscopy have been used with longitudinal and transversal sections (Haematoxylin, Eosin and Safran colorations have been used as well as the Verhoeff coloration for the elastic fibers). Electronic transmission microscopy have also been used.

Clinical applications

Ten percutaneous implantations have been done to eight patients. It concerned five iliac stenosis which have been six months to two years previously dilated and six other superficial femoral stenosis. These stenosis had two to six cm of length and the arteries' diameter above the stenosis were four to six mm.

The stents which have been used, had different sizes too: they had 4.5 to 7 mm of ∅, so that the stent's size adequately fit to the stenosis' length and to the vascular diameter.

The implantation have been done by homolateral femoral retrograde catheterism for iliac stenosis and by direct anterograde puncture for femoral stenosis.

An angioplasty is previously done during one minute with a balloon which diameter is equivalent to the artery's diameter above the stenosis.

A 0.014 inch guide is left in place after the dilatation, while the probe with balloon is pulled out and replaced by the catheter which carries the stents.

The catheter is introduced in the artery with a 6 F introducer.

The stent's release is progressively done under radiologic control. The stent is placed so that it overlaps the stenosis.

An anticoagulant treatment is started a the moment of implantation: 3 to 5000 units of intra arterial heparin. It is then replaced by platelet antiagregating agents during six months (300 mg per day of Aspirin and 70 mg per day of Persantin).

EXPERIMENTAL RESULTS

In all cases (except for 2), the implantation in the desired places was successfull as well in large arteries (iliac or carotid arteries) than in the coronary arteries and the leg tripod's branches. The permeability at a distance from the stent was observed in 37 implantations.

Fourteen animals have been sacrified after angiographic controls. for histological analysis at different moments ranging from several hours to six months after the implantations. This histological analysis allows the evaluation of the tissular reactions towards the stent.

Nine animals have had angiographic controls followed by histological analysis at the ninth month after the implantation.

One animal is still alive to appreciate the evolution of the tissular reactions after one year.

Four animals were dead right away for different reasons totally independant of the stent (like anesthesia accident or local haemorrhage) and they consequently did not have histological analysis. It is important to know that the permeability is related neither to the vessel's type nor to its caliber. Also, the permeability is not modified by the vessel's curves. The collateral branches which are covered by the stent remain permeable.

Finally, the stent's flexibility allows a good adaptability to the vessel's variation during cardiac contractions (coronary arteries).

However, ther are some complications:

— *Mechanical complications* occurred without important consequences.

The outer tube of the carrier catheter have been ruptured in two cases. This led to the use of other catheters. In one case, the outer tube was partially ruptured and the stent was halfly released; but since the distal part of the stent remained firmly fixed to the catheter, it was possible to easily remove the stent.

One failure in coronary arteries catheterism was also noted as well as a vascular traumatism due to the presence of a fixed inflexible guide wire.

Recently, we use a movable and flexible 0.014 inch guide wire.

Neither stent migration nor distal embolisation had occured.

Thrombosis

Ten cases of partial or total thrombosis were observed. They especially occured at the beginning of the experimentations.

In most cases, the thrombosis occured when there is a blood flow perturbation due to the conical shape of the stent's extremity, these thrombosis occur in specific situations when the stent's implantation is not satisfactory:

— When the caliber of the artery's extremity is quickly reduced.

— When the stent's extremity goes through a small collateral branch.

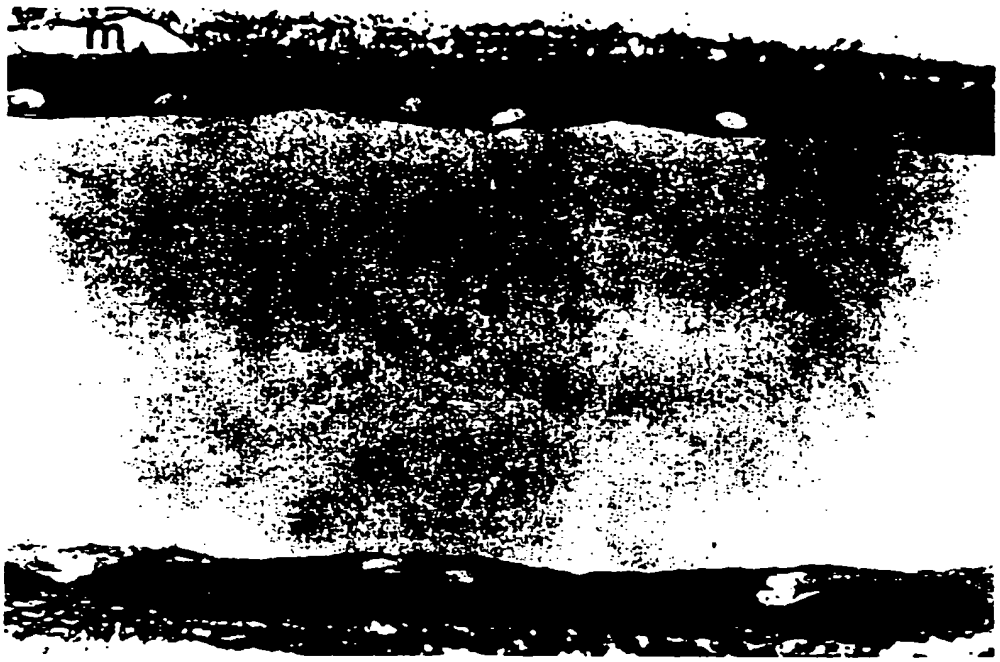

Fig. 2.—The histological results of an experimental carotid implant. 6 months after we note a discret intimal hypertrophy recovering the filament prosthesis. The vascular lumen is regular, and there is no arterial flux perturbation. ni: new intima →; m: media →.

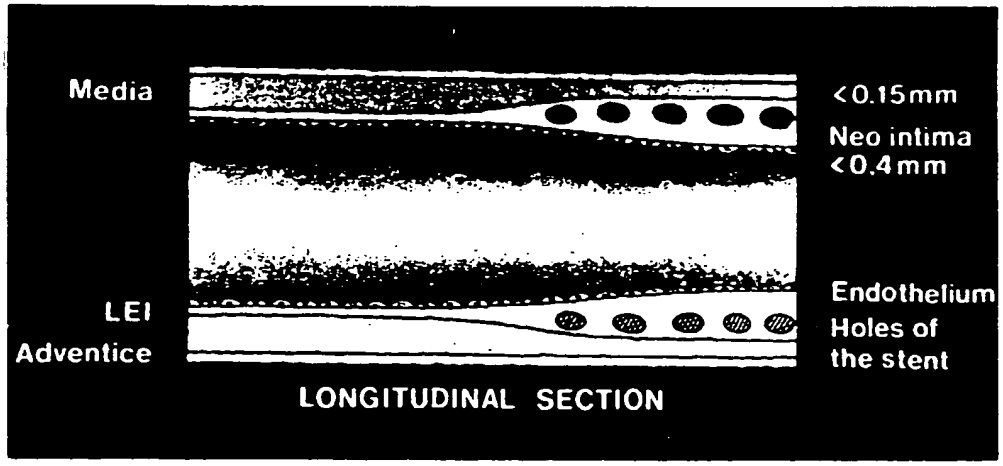

Fig. 3.—Experimental histological results. On a longitudinal section we observed a discret diminution of the medial layer (200±100 microns) with the formation of a neointimal layer (160±130 microns) recovering the prosthesis filament, which in turn is covered by a neo endothelial layer. And so the variability of the lumen diameter could be considered as negligeable.

— When the ratio of the stent's diameter to the artery's diameter is greatly superior to one.

It is interesting to note that in the same conditions of thrombogenicity in one animal, the short stent which perfectly fit to the artery's diameter remain permeable while the stents which do not fit the artery's diameter become conical and lead to thrombosis. The technical improvement of the devices decreases the risk of thrombosis. Thus, there is a very low degree of

Fig. 4.—A stenosis of the superficial femoral artery. The implantation of a 5 mm diameter stent. On a angiographic control done 3 months later we note the persistance of the permeability of a collateral branch which his origin is recovered by the prosthesis.

Fig. 5.—Strong stenosis of the popliteal artery. We have implant a stent of 4.8 mm of diameter. The angiographic control done 10 days after the procedure show the regular aspect of the arterial layers.

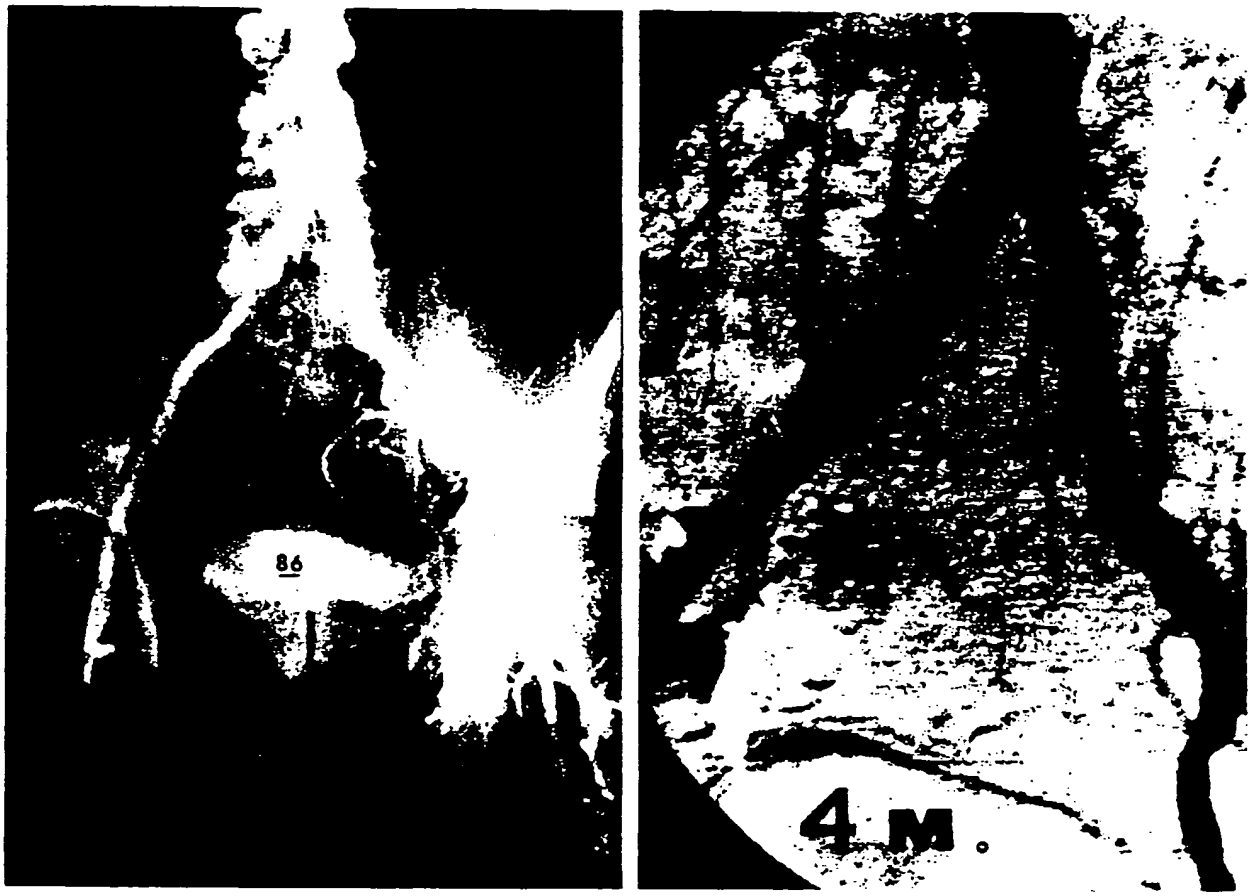

Fig. 6.—Restenosis of the origin of the external iliac artery. Two years after angioplasty, a prosthesis of 6 cm of length and 7 mm of diameter was implanted. An angiographic control done 4 months later show the regular aspect of the vascular layers and the absence of an endoluminal tissular proliferation.

thrombogenicity at the ninth month controls at late implantations.

The following histological results were constantly found in the absence of immediate occlusive thrombosis (see the pictures).

Within the first hours following the implantation, a fibrin and platelet layer with many polynuclear cells is found at the stent's multifilaments implantations. A thin parietal red thrombus which does not reduce the artery's caliber is sometimes found.

One week after the implantation, a translucent membrane, which covers the stent, macroscopically appears. The optical microscopy does not reveal any parietal vascular lesion at the stent's implantation site. Knowing the stent is not fixed to the vascular wall.

At three weeks, the stent lies on the internal elastic membrane without rupturing it. The muscular fibers are included in a thick intimal layer which contains many fibro-elastic cells and a few macrophages loaded with hemosiderin. The endoluminal surface is totally recovered by an endothelium. No evidence of cellular reaction to "foreign body" is found around the stent's filaments.

At six months, the same aspect is found without supplementary proliferation. The new intimal membrane's thickness is of 250 microns when the vascular diameter is five mm.

Other aspects are sometimes found:

— The rupture of the internal elastic membrane (in two cases).

— The clarification of the media's muscular cells which are underneath the filaments.

This cells' clarification corresponds to a localised cellular necrosis.

A parietal necrosis was observed in one case in which an overstreched stent existed.

A slight reaction to foreign bodies have been noticed around the filaments. A layer of macrophages cells which included filings was found (in one case).

An analogous aspect in veins was found with a new intimalisation. However, intravascular, non obstructive septa were present. This is probably due to a veinous hemodynamical status different from the artery's.

Four stents which traverses the collaterals' ostia were histologically studied. The collateral remained permeable. The filaments were surrounded by a new intima without significant reduction of the vascular lumen.

Preliminary clinical results

Among ten implantations, just one partial obliteration of the superficial femoral artery was observed within 3 to 6 months.

This partial obliteration accompanied by collateral branches' development did not need a surgical intervention.

An iliac artery thrombosis had also occured fifteen days after the implantation.

The stent's extremity was lying on a false aneurism at the origin of the iliac artery. This aneurism was due to a first dilatation done two years previously.

The mechanism of secondary thrombosis may be explained by the hemodynamical perturbation at the false aneurism.

In all other cases, angiographic controls have shown the artery's permeability and the presence of a thin, light border between the stent and the lumen. This border compared to the vessel's diameter is negligible.

This border may be considered as a new intimalisation of the stent which is incorporated to the arterial wall.

Neither recurrent stenosis nor stent's migration nor parietal lesion were observed in any of the cases. However these are just preliminary results.

Discussion

The essential problem of angioplasty is the recurrence of stenosis due to the elastic nature of the lesions.

The restenosis frequently depends both on the localisation and on the pathology.

Thus, restenosis are more frequent in the coronary arteries than in the iliac arteries.

Also, they are more frequent in inflammatory arteritis (Takayashu), in post endarterectomy stenosis and in vascular anastomotic stenosis.[19,21]

The failure rate of angioplasty for dialysis A-V fistula stenosis is very significant. This is due to the extensive parietal fibrosis and the intimal hyperplasia.[3,9,10,20]

In order to supply to these dilatations failures, some teams have suggested intravascular stents to maintain the vascular caliber.

In 1969, Charles Dotter put forward a transluminal stent implantation for the first time.[7]

However it is only early 1980 that new principles of stents were worked out.

Dotter again and Gragg reported on some applications of memory alloy spirals which regain its initial form at a certain temperature. However this technique leads to many problems which are not yet solvable.[4,8]

Maass and Wricht, suggested other stents which had elastic properties but were of difficult application.[13,25]

Recently, Palmaz showed the advantage of a stent which is placed on an angioplasty probe with a balloon. When the balloon is inflated, it releases the stent into the lumen.[17,18]

Although this principle is attractive, it shows an inflexibility problem which makes difficult a selective catheterisation.

The principle of stent that we have experimented is totally different.

In fact, it is a metallic, spontaneously expandable stent. When it is percutaneously placed, it is more flexible than an angioplasty proble and therefore easier to use.

The technique was perfectly feasible in all cases. The stents could be placed in arteries of small caliber (3 mm) and of difficult access (like coronary, renal and carotid arteries).

The pressure applied to the wall is previously calculated and adjusted in order to avoid parietal lesion or thrombosis.

Neither migration nor vascular lesion were noted. As equally found by Palmas and Maass's teams, the stent's configuration allows a beginning intimalisation in the first days and a total one after three weeks. This is due to the free spaces between the filaments (approximately 80% of the stent's surface).

A tissular proliferation quickly appears, leading to a perfectly regular and uniform vascular lumen. Thus this tissular proliferation decreases the stents' thrombogenicity and atherogenicity. The collateral branches covered by the stent remain permeable as it was shown in histological and angiographic results.

We should point out that the organism perfectly accepts this alloy since we did not have any inflammatory tissular reaction of rejection.

The preliminary results of the first clinical application seem encouraging.

The stent's implantation does not present any major technical problem and seems harmless.

However there is still certain number of questions:

The action of the stent alone is unknown. Is it possible to use the stent alone without having to previously dilate the stenosis with a balloon probe?

The first observations believe that the centrifugal pressure of the stent alone is not sufficient to immediately dilate most of the stenosis.

It is premature to think that the stent could be systematically used in stenotic lesions.

The good results of angioplasty and the absence of long term results of stenting do not allow to be concluding on this point.

Comparative studies are wished.

However, we look for a certain number of applications:

— Arterial restenosis particularly in the coronary arteries in which the recurrence rate is 30%.

— Arterial stenosis which are classically not accessible to angioplasty such as carotid or vertebral artery stenosis, because of the emboligenous risk.

(Theorically, the stents allow the dilatation by imobilising the atheromatous lesions. If the first dilatation by the stent alone is not sufficient, we can look for a second dilatation by an angioplastic balloon inside the stent's lumen).

— Gianturco *et al.* have suggested the treatment of aortic dissections by the stents.

— Veinous applications can also be done, such as the treatment of extrinsic compression by a local tumor or by perivascular fibrosis. These extrinsic compressions lead generally to cava syndrome.

— Long and irregular stenosis of dialysis A-V fistula. These stenosis are not actually accessible to angioplasty.

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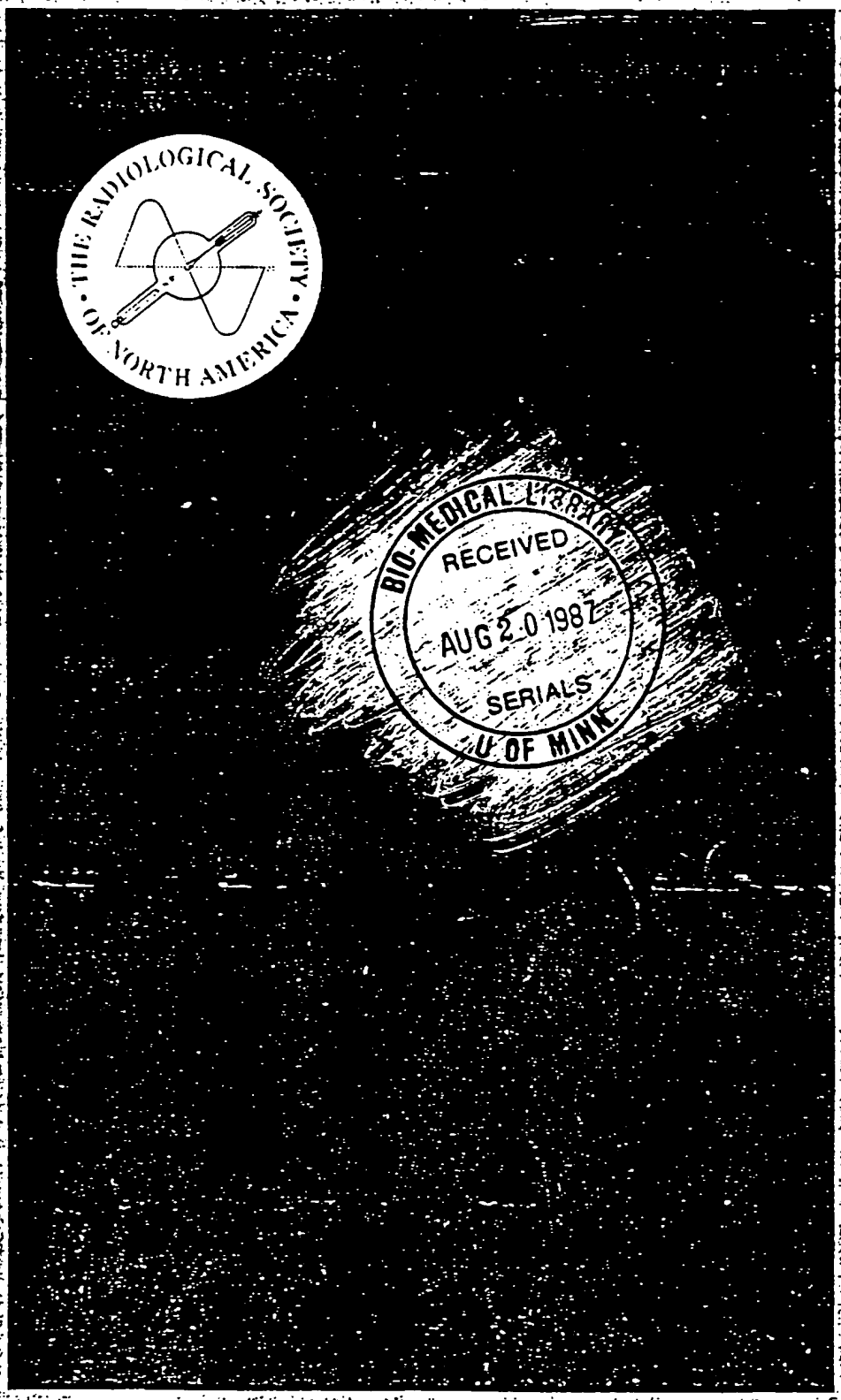
Radiology



73rd Scientific Assembly and Annual Meeting
Chicago, November 29 – December 4, 1987

Hervé Rousseau, MD • Jacques Puel, MD • Francis Joffre, MD • Ulrich Sigwart, MD • Christophe Duboucher, MD • Christian Imbert, BS • Christopher Knight, PhD • Laurent Kropf, BS • Hans Wallsten, MS

Self-expanding Endovascular Prosthesis: An Experimental Study[1]

A new type of endovascular prosthesis was inserted in 28 animals and evaluated for several factors, including thrombogenicity, tendency to migrate, critical implant zones, and incorporation into the vascular wall. The new prosthesis is a woven, multifilament structure of stainless steel alloy; its inherent elastic, self-expanding characteristics hold it against the vessel walls. Forty-seven endoprostheses (3-5 mm in diameter, 15-50 mm long) were percutaneously implanted with either a 6-F introducer sheath, a coaxial 9-F catheter, or a 0.014-inch (0.036-cm) guide wire into the femoropopliteal, coronary, carotid, and renal arteries and iliac veins. Anticoagulant or platelet antiaggregating agents were not used before or after implantation. Angiographic and histologic analyses showed that the prosthesis had a very low thrombogenicity when it was well adapted to the native vessel diameter and that it was incorporated into the vessel wall by a new intima by the 3d week after implantation. No migration occurred, and branch vessel flow was preserved even in those vessels in which ostia were traversed by the prosthesis. This prosthesis has potential for clinical application in the treatment of postangioplasty restenoses, particularly in the coronary arteries.

Index terms: Arteries, grafts and prostheses, 90.456 • Arteries, interventional procedure, 90.1299 • Coronary vessels, interventional procedure, 54.1299 • Veins, grafts and prostheses

Radiology 1987; 164:709-714

ANGIOPLASTY, although highly successful and a major contribution to the medical armamentarium, is not without important limitations, among which is a high frequency of restenosis associated with coronary and femoral dilations. Consequently, the use of an expandable, parietal scaffolding device or stent prosthesis seems to be a logical and attractive approach to preventing restenosis over the long term and in stabilizing patency-threatening intimal dissections in the shorter term.

As early as 1969, Dotter (1) reported on transluminal implantation of a metal spiral prosthesis in the canine popliteal artery, but only recently has more extensive research been undertaken.

We report on our experience with 47 in vivo percutaneous implantations with a new form of self-expanding prosthesis and its specially designed delivery system. The objectives of our evaluation were twofold: (*a*) to determine, starting from the first single-size stent model, the optimal ratio of implanted to unconstrained diameter; and (*b*) to determine the thrombogenicity, critical implant zones, geometric stability, tendency to migrate, and mechanism of prosthesis incorporation into the vascular wall.

MATERIALS AND METHODS

The endovascular prosthesis (stent) (Medinvent SA, Lausanne, Switzerland) is a woven, multifilament structure composed of a high-performance, medical-grade, stainless steel alloy. Because of the elasticity of the individual metal filaments and of the structure itself, the stent may be stretched longitudinally and constrained to a small diameter within its delivery device. Controllable, progressive deployment of the stent from the delivery instrument permits the prosthesis to expand spontaneously and affix itself against the internal vascular wall.

Mural pressure generated between the prosthesis and the vessel wall is a function of metal properties, filament diameter, and the ratio of the unconstrained diameter of the prosthesis to its implanted diameter.

Early models of the delivery system had fixed guide wire elements attached to the instrument tip, while later devices were adapted to receive a 0.014-inch (0.036-cm) movable guide wire (Fig. 1). Prosthesis retention in the delivery system is effected by means of an invaginated balloonlike structure connected to a pressure manometer. Low hydraulic pressure of 3.5 bar (0.35 MPa) and control with a distal slide mechanism are used to permit almost frictionless eversion of the constraining membrane in such a manner as to permit progressive release of the prosthesis (Fig. 2). If the hydraulic pressure is removed from the annular channel of the coaxial system, the prosthesis is tenaciously held within the instrument tip, even if only a small portion of the stent remains to be deployed.

Forty-seven stents, 15–50 mm long and 3–5 mm in diameter, were implanted in the iliac, femoral, axillary, renal, carotid, and coronary arteries and in the iliac veins of ten sheep and 18 dogs (Table 1).

General anesthesia was induced in the animals with 20 mg/kg Pentothal sodium (thiopental sodium; Abbott, North Chicago, Ill.), and femoral arteriotomy was performed for better control of intraoperative bleeding or percutaneous femoral access. Selective angiography was used to determine vessel diameter. Prostheses were inserted in the coronary artery via a 9-F guiding catheter and in other vessels solely by delivery over the 0.014-inch guide wire.

Implant sites were specifically chosen to be particularly challenging: for example, across large and small branches in or-

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See also the article by Palmaz et al. (pp. 705-708) in this issue.

Table 1
Summary of Implantation Data and Outcome in 28 Animals

No.	Unconstrained Prosthesis Dimensions (mm)	Implantation			Outcome	
		Vessel Diameter (mm)	Site	Ratio*	Radiologic	Histologic†
1	3.5 × 20	3	Popliteal		Normal, 4 mo	Living
	3.5 × 20	3.2	Femoral		Normal, 4 mo	
	5 × 40	3.2	Femoral	>1.5	Thrombosed (conicity)	
2	3.5 × 20	3	Popliteal		Normal, 4 mo	Living
	3.5 × 20	3.5	Femoral		Normal, 4 mo	
	5 × 40	3	Popliteal	>1.5	Thrombosed (conicity)	
3	3.5 × 20	3	Femoral		Normal, 4 mo	Living
	3.5 × 20	3	Femoral		Normal, 4 mo	
	3.5 × 30	2.8	Popliteal		Normal, 4 mo	
4	3 × 15	3	Femoral		Local hemorrhagic death	NA
	3 × 15	2.5	Popliteal			
5	3.5 × 20	3	Coronary		Anesthetic death	NA
6	3.5 × 20	3	Coronary		Normal, 1 mo	Reendothelium
7	4 × 20	3	Renal		Normal, 45 d; patent collaterals	Reendothelium
8	5 × 20	4	Coronary		Normal, 10 d	Early reendothelium
9	5 × 30	4	Coronary		Normal, 10 d	Early reendothelium
	5 × 30	4.2	Renal		Normal, 10 d	Early reendothelium
10	5 × 30	3.5	Coronary		Thrombosed, 1 wk	NA
	5 × 30	4	Renal		Thrombosed, 1 wk	NA
11	5 × 30	2.5	Popliteal	>1.5	Thrombosed (conicity)	Old thrombus
	5 × 30	2.5	Popliteal	>1.5	Thrombosed (conicity)	Old thrombus
	5 × 30	5	V. iliac		Thrombosed (conicity)	Old thrombus
12	6 × 15	4	Coronary	>1.5	Normal, 3 mo	NA
13	5 × 15	3.5	Coronary		Normal, 3 mo	Living
14	5 × 40	4.5	Carotid		Normal, 6 mo	Reendothelium
	5 × 50	2.5	Popliteal	>1.5	Irregular, 6 mo	Partial thrombosis
	5 × 50	4	V. iliac		Parietal thrombus	Flow partition
15	5 × 15	3.5	Coronary		Anesthetic death	NA
16	5 × 15	3.5	Coronary		Normal, 2 mo	Reendothelium
17	5 × 15	4	Coronary		Thrombosis; stent in marginal branch	Infarct, thrombosis
18	5 × 15	3.5	Coronary		Thrombosis; stent in marginal branch	Infarct, thrombosis
19	5 × 15	3.5	Coronary		Normal, 6 mo	Reendothelium
	5 × 15	4	Coronary		Normal, 6 mo	Reendothelium
20	5 × 50	3.2	Carotid	>1.5	Partial thrombosis	Partial thrombosis
	5 × 50	3.2	Carotid	>1.5	Partial thrombosis	Partial thrombosis
	5 × 50	3	Axillary	>1.5	Thrombosis	Thrombosis
	5 × 30	4	Iliac		Normal, 45 d	Reendothelium
	6 × 40	4	V. iliac		Normal, 45 d	Reendothelium
21	5 × 15	3.5	Coronary		Stent in marginal branch	Thrombosis, infarct
22	5 × 15	4	Renal		Normal, 3 mo	Living
	5 × 15	3.5	Coronary		Normal, 3 mo	
23	5 × 15	3	Coronary		Patent, 1 wk; conicity	Early reendothelium
24	5 × 20	3.5	Coronary		Normal, 3 mo	Living
25	5 × 20	3.5	Coronary		Normal, 3 mo	Living
26	5 × 20	4	Coronary		Normal, 3 mo	Living
27	5 × 20	4	Coronary		Normal, 3 mo	Living
28	5 × 20	3.5	Coronary		Normal, 3 mo	Living

Note.—NA = not applicable, V = venous.
* Only ratios greater than 1.5 are indicated; all other values were less than 1.5.
† Reendothelium refers to the covering of the endoluminal surface by a new endothelium.

der to determine thrombogenicity or patency and in zones of vascular curvature, potential kinking, or flexion in order to gain an understanding of the risks of thrombogenesis and ulceration in the smaller arteries (coronary and popliteal). Anticoagulants were administered only intraoperatively, and neither anticoagulants, antiplatelet agents, nor calcium antagonist agents were used pre- or postoperatively. The objective was to assess the inherent thrombogenicity of the prosthesis as well as tissue reaction.

Angiographic follow-up studies were conducted a few hours, 10 days, 1 month, 3 months, and 6 months after implantation. Macroscopic and microscopic histologic analyses were performed immediately following angiographic study in order to establish the mechanism and evolution of stent-tissue interaction.

Light microscopic examination consisted of transverse and longitudinal sections (with hematoxylin-eosin-safranine and Verhoeff stains), and transmission electron micrographs were also prepared.

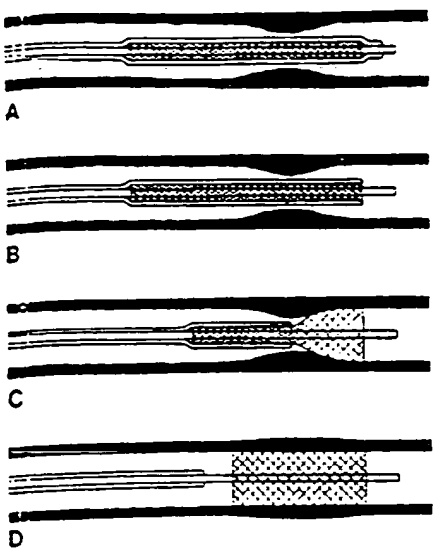
RESULTS

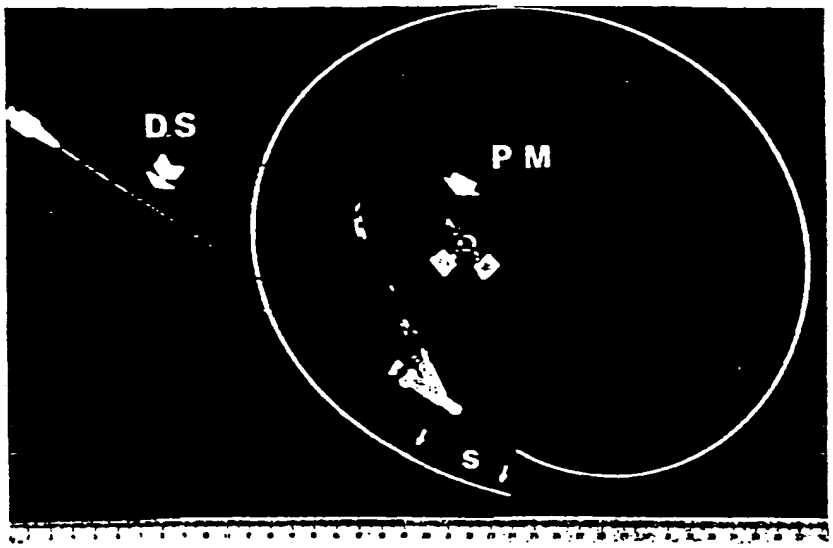
Fourteen animals were killed after angiographic study for histologic analysis. Three acute deaths occurred for reasons totally independent of the prosthesis (accidents of anesthesia, local hemorrhage), and in these animals histologic analysis was not done. Ten animals were retained for longer term survival, all having angiographically proved patency at 3 months or more. The patency of the prostheses was confirmed in 27 implants.

It is particularly noteworthy that patency seemed unrelated to vessel type and caliber (Figs. 3, 4). Patency was also not influenced by vessel curvature, as branch vessels traversed by the prosthesis remained patent (Fig. 5). The flexibility of the stent allowed it to adjust easily to the flexion of the vessels during cardiac contractions. No case of stent migration or embolization was seen.

Complications

Access.—Implantation at the desired site was successful in all cases but one. One of the early fixed guide





1.gures 1, 2. (1) Diagram shows the endovascular prosthesis constrained to a small diameter by an invaginated balloonlike structure. The 5-F delivery system is introduced through a 6-F introducer or, for coronary implants, through a 9-F catheter (*A*). Inside the catheter we can place a 0.014-inch movable guide wire. Low hydraulic pressure is used to permit progressive release of the prosthesis (*B*). Controllable, progressive deployment of the device from the instrument permits spontaneous expansion of the prosthesis (*C*) and fixation of it against the internal vessel wall (*D*). (2) Stent (*S*) retention at the end of the delivery system (*DS*) is effected by a constraining membrane connected to a manometer (*PM*) that can be inflated like an angioplasty balloon. Low hydraulic pressure permits almost frictionless eversion of this membrane of the main catheter and progressive release of the stent.

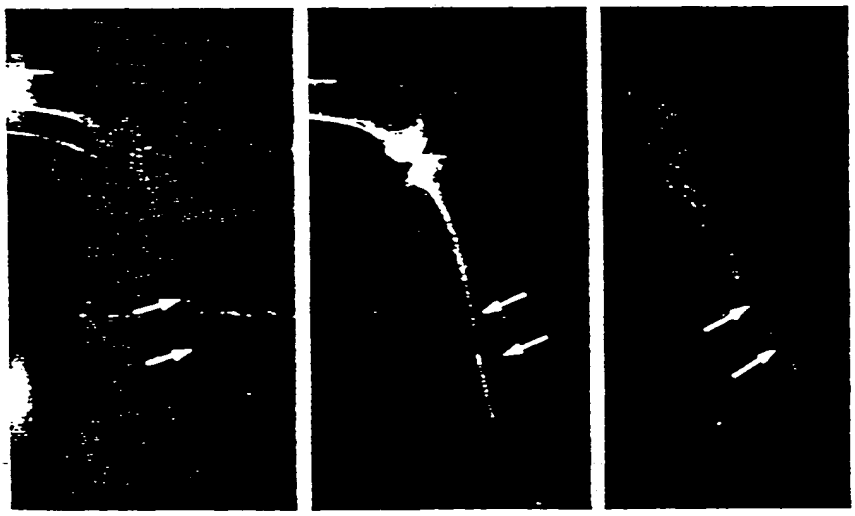


Figure 3. (a) Tibial artery implantation. The endoprosthesis (3 × 15 mm), in its constrained format, lies over a 0.014-inch guide wire (arrows). (b) Stent in place (arrows). (c) Follow-up angiogram shows good distal runoff. Note congruence of the stent diameter with that of the native vessel.

ire instruments could not be moved ..noothly to the target site, and it induced a dissection. Access difficulties with the fixed guide wire were sufficiently common that a movable guide wire instrument was developed that essentially eliminated these problems and was used in later implantations. In general, mechanically based complications were of little consequence. In two cases a rup-..re of the invaginated, saline-filled retaining membrane occurred and led to use of a second instrument. In one of the cases the prosthesis had been partially released, but, since the proximal part of the prosthesis was still firmly attached to the delivery system, both stent and delivery system were easily removed.

Thrombosis.—Partial or total thrombosis was seen in eight animals, especially at the beginning of our study when early model prostheses were used. In most cases the thromboses were induced due to conicity of the edges of the stent (which significantly reduced vessel caliber) and to the perturbations that this induced in the blood flow. These thrombotic complications were seen in very specific situations: (*a*) a point of very rapid reduction in vessel diameter, (*b*) when the end of the prosthesis was engaged in a side branch of a main vessel, and (*c*) when the ratio of unconstrained to implanted diameters was greater than 1.5.

The example of animal 20 is typical in that short stents of well-adapted diameters remained perfectly patent, while in the same animal long stents in a vessel that was too small led to conicity and thrombosis (Fig. 6).

A significant technical development was made by the manufacturer to avoid the problem of conicity, and this led to consistently better results in the later part of the study.

Histologic Analysis

In the absence of immediate occlusive thrombosis, the following results were consistently obtained in histologic examinations performed after implantation.

First few hours.—A thin fibrin and platelet layer formed over the prosthesis with evidence of polymorphonuclear leukocytes localized at the prosthesis filaments. Sometimes a

thin, discrete, red, parietal thrombus was seen adhering to the filaments, but it was too small to influence the caliber of the vessel.

One week.—Macroscopic examination revealed a thin translucent membrane covering the stent. Light microscopy showed the absence of a parietal lesion in the region of the stent, and the stent was not fixed to the wall.

Three weeks.—The stent was found to be lying against the internal elastic membrane without rupturing it. The thickened intima was rich in fibroelastic cells and contained a few hemosiderin-laden macrophages. The endoluminal surface was totally covered by endothelium, and no evidence of "foreign-body" cellular reaction was seen around the prosthesis filaments.

Six months.—Findings identical to those seen at 3 weeks were noted without signs of significant progression of the neointimal thickness. This was found to be of the order of 250 μ for a vessel diameter of 5 mm. In our studies the intimal thickness was found to vary from a minimum of 50 μ to a maximum of about 400 μ (Fig. 7).

Three stents traversing the ostia of branch arterial vessels were studied histologically. All branches were patent, with the metal filaments individually enclosed by neointima without significant reduction of the vascular lumen (Fig. 8).

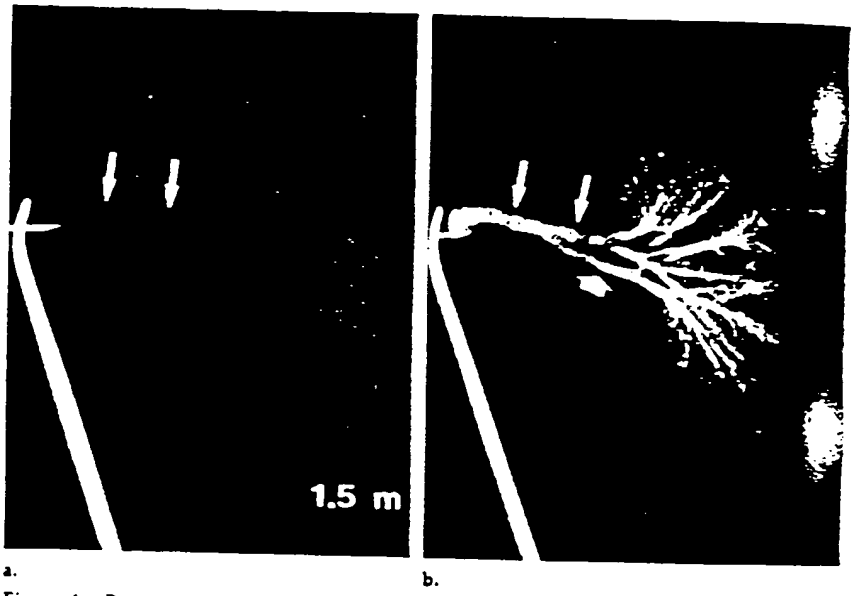
In the three venous implants, a neointima analogous to that found in the arteries was seen. In addition, however, we also noted nonocclusive thrombi stretched across the lumen and dividing the flow into two channels. To our knowledge, this finding has not been previously reported by others working with stents in the venous system; hence, the question remains to be studied in greater detail.

Other exceptional findings included rupture of the internal elastic membrane in two cases, localized cellular necroses of the layer beneath the stent due to a high mural pressure in some cases, mural necrosis in one case (animal 11) in which there was an evident overcompression of the prosthesis (ratio, >1.5), and a foreign-body reaction near a metal filament due to the presence of a contaminating particle of unknown origin in one case.

DISCUSSION

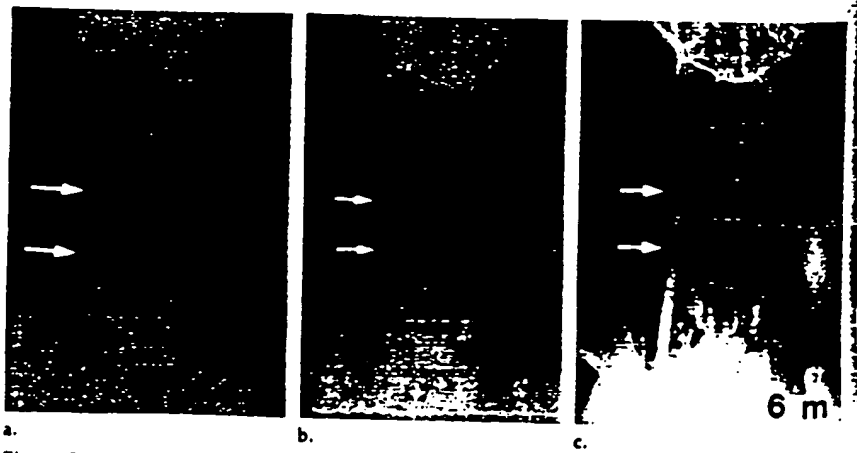
As a result of these preliminary experiments, we can hypothesize the sequence of reactions after implantation between the blood, vessel wall, and prosthesis. In the first few hours of contact, a fibrin- and platelet-rich thrombus of about 150-μ thickness adheres to the metal filaments of the prosthesis. This thrombus is related to local flow perturbations and the liberation of thrombogenic factors caused by loss of the endothelial cells and the exposure of the basement membrane. The thrombus has a tendency to cover the zones of turbulence and the irregularities of the vessel wall. Subsequently, organization of the thrombus occurs by colonization with histiocytes and then with macrophages and fibroblasts. Concomitantly, surface endothelialization occurs. In the final phase of the process (after 1 month), a stable fibrous tissue is formed, containing only myofibroblasts, with a clear absence of inflammatory cells. One interesting finding in cases of acute thrombosis was the development of multiple small-bore channels noted in angiographic and histologic controls (e.g., animal 20).

A significant limitation of angioplasty is restenosis, and in some instances this is due to the elastic na-



a. b.

Figure 4. Postmortem angiograms of a renal artery prosthesis (2 × 20 mm). Animal was killed at 45 days after implantation. (a) Note smooth aspect of transprosthesis flow, with the ends of the prosthesis slightly flared (arrows). *1.5 m* = 1.5 months. (b) Angiogram shows patency of the renal artery and the inferior arterial branch covered by the prosthesis. No sign of renal cortex ischemia was found (arrows). Histologically, a perfect neointima was found without trace of any parietal lesion.



a. b. c.

Figure 5. Animal 14. Angiograms show introduction of a carotid prosthesis (5 × 40 mm) via femoral access. (a) Implantation; note presence of guide wire (arrows). (b) Stent deployment; note absence of flaring at ends of the prosthesis (arrows). (c) At 6 months follow-up (*6 m*), no modification of the artery is seen, and there is excellent distal runoff (arrows).

ture of the lesions. The likelihood of restenosis occurring is dependent on both underlying disease and location (2–4). Thus, the frequency of restenosis is greater in the coronary arteries than in the iliac arteries, and inflammatory (Takayasu) arteritis (5), vascular anastomotic stenoses, and post-endarterectomy (6) stenoses tend to have a particularly high recurrence rate. The frequency of angioplasty failure in cases of dialysis arteriovenous fistulas is very significant (7–12) due to extensive parietal fibrosis and intimal hyperplasia (13). To overcome these dilation failures, several groups have worked with endovascular prostheses with the objective of maintaining the vascular lumen diameter.

In 1969 Dotter (1) reported on the first in vivo endovascular prosthesis implants. Dotter et al. (14) and Cragg et al. (15) then reported on the use of nitinol memory metal as a means of spontaneously converting an extruded metal filament into a spiral stent at 37°C. Various technical problems associated with the device and its performance in vivo have apparently stymied development of this otherwise potentially attractive approach. In both studies (14, 15), luminal narrowing caused by fibrin deposition was apparently a common problem.

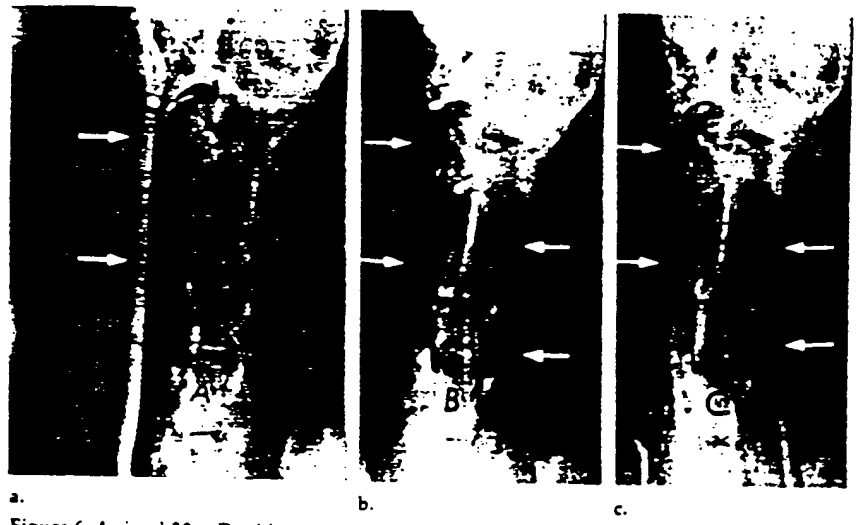
Maass et al. (16) and Wright et al. (17) worked with elastic, self-expanding prostheses of relatively large dimensions. Both groups noted that their implanted prostheses were covered by intimal proliferation and endothelialization of the metal surface, leading to good resistance to restenosis. No mural erosion was noted, collateral vessels were found to be patent, and limited cell growth on metal filaments bridging vessel ostia was also seen.

Recently Palmaz et al. (18, 19) have reported on the use of an expandable device designed on the basis of the expansion metal principle. Although the principle is quite attractive, the relative rigidity of the device suggests that selective catheterization and stenting tight bends or long curves might be difficult.

Palmaz et al. (18) used soldered mesh prostheses (a relatively noncompliant structure) and reported on two of 11 canine implants that led to intimal hyperplasia; they observed 38% and 30% stenosis in stents of 6- and 10-mm diameters, respectively, at 2 months follow-up. They raised the question as to whether excessive compliance mismatch at the point of transition between artery and stent could lead to turbulence and neointimal proliferation.

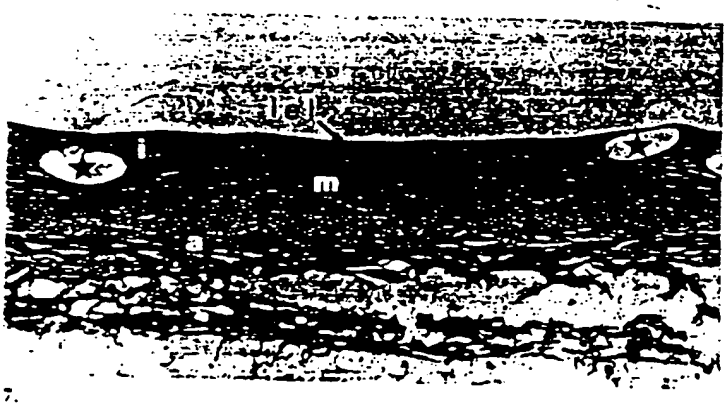
The endoprosthesis used in our experiments is totally different from any of the prostheses mentioned above, in both configuration and its inherent properties. It is radially self-expanding and longitudinally flexible in both the implanted and catheter-mounted conformations. The instrument is specifically adapted to existing angioplasty accessory equipment such as coronary guiding catheters and guide wires, and implantation does not necessitate an interruption in coronary flow.

Our 47 implantations were made with delivery instruments and pros-



a. b. c.

Figure 6. Animal 20. Double carotid implantation (5 × 50 mm). (a) During right common carotid implantation, angiogram shows an overdistention of the artery (arrows). (b, c) Angiograms obtained at 45 days. The ends of the stent are conical (arrows), and the angiograms show partial stent thrombosis with partial distal opacification. Histologic examination revealed partial thrombosis, with multiple, small-bore channels. The stent is badly adapted to arterial diameter; this leads to the conicity of the trailing edges.



7.

8.

Figures 7, 8. (7) Histologic specimen (hematoxylin-eosin-safranine stain; original magnification, ×100) of carotid artery (animal 14) 6 months after implantation. Neointima (*i*) totally covers the metal filaments, and the vessel lumen is smooth and regular. The internal elastic lamina (*iel*, arrow) is intact. The media (*m*) is indented but without sign of necrosis or rupture. *a* = adventitia, ★ = holes of the stent (after the filaments are removed). (8) Histologic section (hematoxylin-eosin-safranine stain; original magnification, ×25) of an iliac stent lying over patent lumbar branch arteries. Neointima (arrows) is seen over entire endoprosthesis and the ostial filaments (arrowheads). • = main vessel lumen and collateral branch (both are patent).

theses of progressively modified and improved characteristics. However, certain consistent findings specific to the fundamental concept were found. First, the ease of access and implantation was surprisingly good, with successful implantations accomplished in small arteries even via difficult access (circumflex, renal, or carotid arteries). Accidental triggering of the release mechanism during access manipulation was not possible, so we had no incidence of accidental discharge of the device. The fact that a partially deployed prosthesis can be retrieved is a useful feature. The design of the prosthesis is such that the force exerted on the vessel wall is evenly distributed; thus, there are no regions of localized high pressure or segments of unsupported vessel wall. The self-expandable nature of the device and its high, inherent, geometric stability minimized the risk of prosthesis migration. Radiologic studies confirmed that there was no migration or movement of the stent, although we did detect some very minor prosthesis dilatation and shortening.

Since about 80% of the surface area of the prosthesis is essentially space between metal filaments, new intima developed quickly in a manner analogous to that seen by Maass et al. (16), Palmaz et al. (18), and Wright et al. (17). Maass et al. found that complete covering of the prosthesis occurred at 3–4 weeks, with total stabilization of the intimal thickening and healing process at 3–4 months, confirmed at follow-up at 2 years or more. The thickness of the intima in the latter case was 250–450 μ. The growth process we saw resulted in an intima 150 μ thick at 3 weeks (thus totally encapsulating the 80-μ-thick metal filaments rapidly), and at 9 months the intima was stable at a thickness of 50–400 μ. It appears, therefore, that intimal covering occurs more rapidly for metal filaments of smaller diameter, at least for flexible self-expanding prostheses.

Finally, we found that the arterial wall had excellent tolerance for the stent alloy, with a consistent absence of inflammatory reaction.

Although our experimental study was preliminary because it was conducted in healthy animal arteries, it spanned a number of important steps in the technical development of the implant material. The implantation of this stent in diseased vessels of experimental animals is under further study.

This experimental study showed us the feasibility of the technique and the perfect vascular tolerance of the prosthesis. The principal potential clinical application appears to be in treating postangioplasty restenoses, particularly in coronary arteries where the recurrence rate is known to be high (30% or more depending on lesion location). Another application would be in treating arterial lesions that are traditionally excluded from angioplasty, such as carotid or vertebral artery stenoses for which the risk of embolization is believed to be significant. In principle, the stent could be used as a protective barrier to immobilize fragments of the atheromatous plaque.

Charnsangavej et al. (20) have proposed endovascular stenting of aortic dissections. We foresee that venous applications, such as the treatment of extrinsic tumoral or fibrotic compression of the vena cava causing superior vena cava syndrome, may be possible. Similarly, the long and irregular stenoses caused by dialysis arteriovenous fistulas that currently have a poor prognosis with angioplasty therapy may be worthy of attention. Palmaz et al. (21) have performed preliminary work on the stenting of portacaval shunts in which the stent lies against the liver parenchyma rather than the tissue of a vein or artery. ■

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United States Patent [19]

Wiktor

[11] Patent Number: 4,969,458

[45] Date of Patent: Nov. 13, 1990

[54] INTRACORONARY STENT AND METHOD OF SIMULTANEOUS ANGIOPLASTY AND STENT IMPLANT

[75] Inventor: Donald M. Wiktor, Cranford, N.J.

[73] Assignee: Medtronic, Inc., Minneapolis, Minn.

[21] Appl. No.: 69,536

[22] Filed: Jul. 6, 1987

[51] Int. Cl.[4] A61M 29/02

[52] U.S. Cl. 606/194; 623/13; 606/108

[58] Field of Search ..... 128/334 R, 341-344; 623/13

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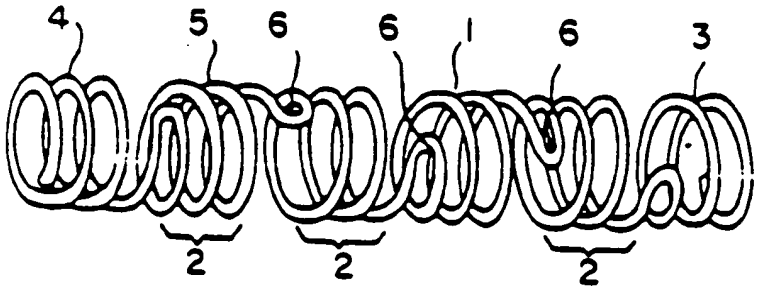
Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Robert J. Klepinski; Joseph F. Breimayer

[57] ABSTRACT

A device to be used as a vascular stent comprising a cylindrical open-ended wire component made of a low memory metal such as copper alloy, titanium, or gold, providing a radial support from within a blood vessel after implantation therein. The coronary stent is characterized by its ability to be expanded radially to a larger diameter after initial implantation and means for causing said stent to expand to a larger diameter and a method for transporting, positioning and implantation of such coronary stent transluminally to have said stent act as a permanent prosthesis to assure vascular patency. And method for simultaneous angipolarty and stent implant procedure.

10 Claims, 2 Drawing Sheets



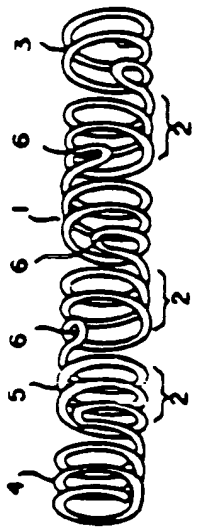


FIG. 1

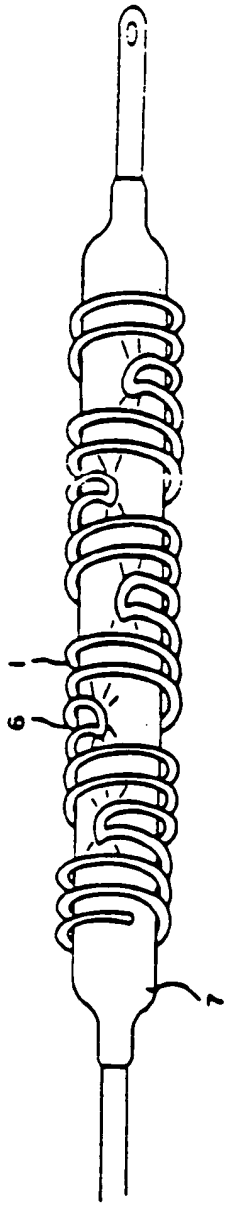


FIG. 2

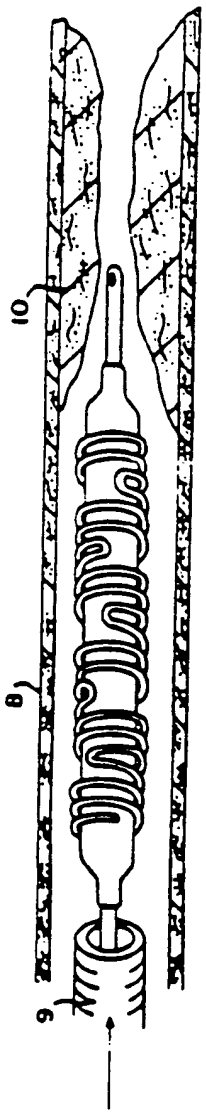


FIG. 3

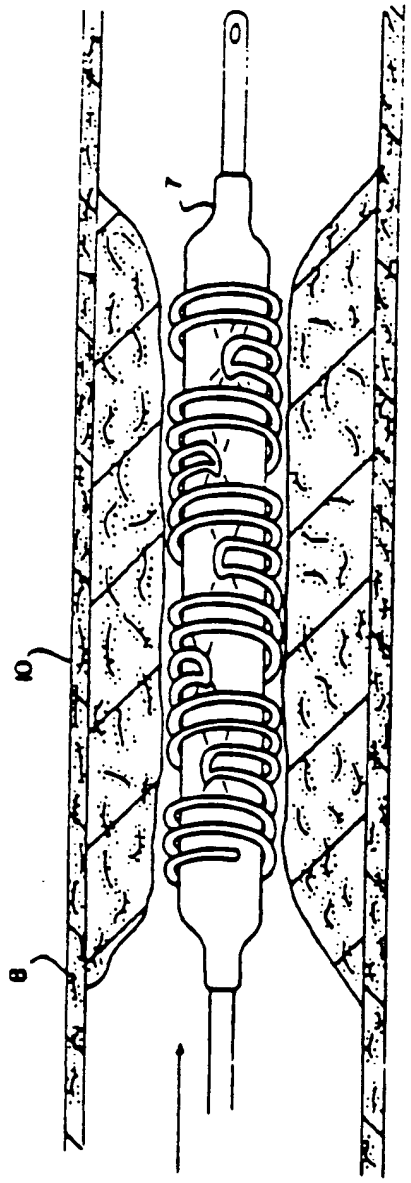


FIG. 4

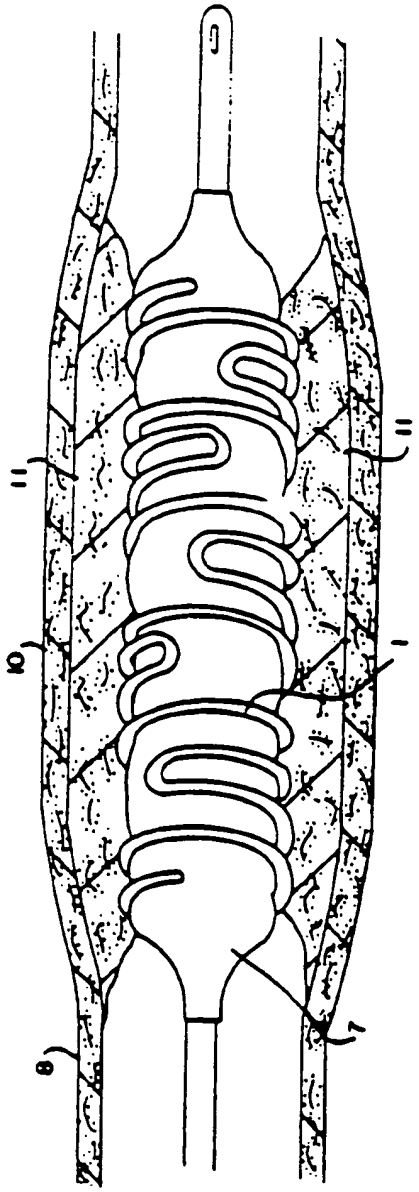


FIG. 5

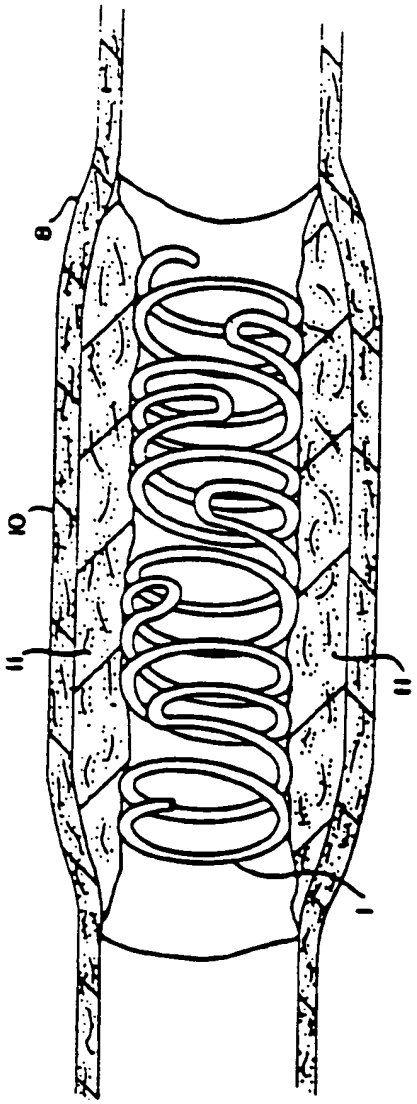


FIG. 6

INTRACORONARY STENT AND METHOD OF SIMULTANEOUS ANGIOPLASTY AND STENT IMPLANT

FIELD OF THE INVENTION

This invention relates to intravascular implants for maintaining vascular patency in humans and animals. The present invention comprises an open-ended wire formed device of basically cylindrical shape and made of a softer-than spring type metal and fitted over an inflatable element of a typical balloon type catheter such as described in U.S. Pat. No. 4,195,637 and U.S. Pat. No. 4,402,307. The wire formed device is intended to act as a permanent prosthesis stent and is implanted transluminally. Specifically this invention is characterized by the ability of said intravascular stent to be enlarged radially after having been introduced percutaneously, transported transluminally and positioned at a desired location. In addition, this invention relates to a method whereby a permanent prosthesis stent is implanted at the same time the angioplasty procedure is being performed. This invention is particularly useful in transluminal implantation of a stent in the field of cardiology and especially in the case of coronary angioplasty to prevent restenosis.

BACKGROUND OF THE INVENTION

In my U.S. Pat. No. 4,649,922 a device is described in combination with a catheter which is basically a compressed spring retained between a partially inflated balloon and an abutment immediately behind the balloon on the catheter shaft. The intent is to transport the spring prosthesis in this manner to the desired location and then after a successful angioplasty procedure release said spring prosthesis by totally evacuating said balloon, thus allowing said spring prosthesis to expand linearly and stay in place while the balloon catheter is withdrawn. This method is quite simple and its simplicity is very attractive; however it has some drawbacks. One and foremost is the fact that the spring has a fixed diameter and as such is unable to fully conform to the inside wall of the vessel which at times is quite tortuous and thus could conceivably create a somewhat turbulant flow of blood, and possible thrombosis could in some cases result. Other Patents, e.g. No. 4,553,545 teach a different method where a relatively complex mechanical rotating device and co-axial cables are employed to achieve the necessary means to change the diameter of the implanted stent to a larger dimension at the point of implant. Still other Patents, e.g. No. 3,868,956 describe a method wherein a temperature responsive metallic device is used and expanded after implant using external heat sources. All of the above mentioned devices present drawbacks of various magnitudes including blood coagulation and possible thrombosis, and considerable complexity of procedure.

In angioplasty procedures at this time, in many cases restenosis occurs soon thereafter, which requires a secondary procedure or a surgical bypass operation. The implanted prosthesis as described herein will preclude such additional procedures and will maintain vascular patency indefinately.

Depending on the size used, the device according to this invention can also be efficacious in other, similar applications, such as: repair of aneurisms, support of artificial vessels or liners of vessels, stabilization of interior vessel tubes, e.g. bronchial tubes, retention of emboli and plaque and mechanical support to prevent collapsing of dialated vessels. Still many other and similar applications will be manified by this invention without departing from the basic premise and concept.

This device particularly allows a single percutaneous transluminal angioplasty procedure to combine the essential angioplasty itself using any standard balloon-type catheter to recanalize an obstructed vessel with the implantation of a permanent prosthesis stent in one single procedure thereby reducing the risk factor and the trauma by a considerable degree for the patent undergoing such procedure.

Other reference publications:

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3. U.S. Pat. No. 4,580,568 Percutaneous endovascular stent.

4. U.S. Pat. No. 4,503,569 transluminally placed expandable graft prosthesis Dotter 1985.

5. U.S. Pat. No. 4,699,922 Catheter arrangement having a variable diameter tip and spring prosthesis, Wiktor 1987.

All of the above references describe or teach various methods of providing or otherwise introducing stents or different types for applications similar to one described in this invention.

SUMMARY OF THE INVENTION

The improvement of this invention over other similar devices such as cited in patents above, and specifically my previous invention described in U.S. Pat. No. 4,649,922, is the ability of the device of this invention to allow for and to maintain a very low profile and a small frontal area, so very important for purposes of percutaneous insertion. Thus the stent of this invention can be inserted into and be transported via a standard #8F Guiding Catheter such as USCI Cat. #006128, while using standard procedures and methods. Once on location, the stent can be expanded radially to a diameter larger then initially introduced: a ratio of 2½:1 can easily be achieved with a wire diameter of 0.008 and initial stent diameter of 0.075. The expanded larger diameter will conform to the inside of the vessel and maintain intimate contact with the inside wall. The stent of this invention is characterized by the low memory level of the relatively easily deformable metal used for the wire.

The configuration of the stent 1, shown in FIG. 1, is such that the wire 3 is coiled having a limited number of turns wound in one direction 4 then reversed and wound in the opposite direction 5 with the same number of turns, then reversed again and so on until a desired length L is obtained. In order to create this stent 1 and to assume the configuration as shown in FIG. 1 a length of selected wire is wound on a mandrel of given diameter for 3 turns stpped and reversed forming a tight loop 6 of approximately 3–4 wire diameters. At this point pressure is applied to inside of loop 6 with a pressure finger (not shown) to prevent the wire from unwinding when the direction of winding is reversed.

The purpose of having only a limited number of turns wound in one direction then reversed and having the same number of turns wound in the opposite direction is

to allow for radial expansion of stent 1 when controlled pressure, such as applied by an inflated balloon 7, is applied from the inside of said stent 1.

This condition is well illustrated in FIG. 5. The radial expansion is achieved and accomplished by partial uncoiling and unwinding of one or two turns or parts thereof until a larger diameter is obtained. The dimensions of the enlarged diameter is dictated and determined by the diameter to which the balloon is inflated. By comparison, a typical coil spring, in which all of the coils are wound in the same direction, cannot readily be expanded radially regardless of the magnitude of pressure applied to the inside of such coil spring, due to considerable friction between the coils and the surrounded media such as the balloon. The friction of a coil spring around any object increases exponentially with number of turns. Such principle is typically used on a capstan. In my invention, characterized by the construction and configuration of the stent 1, the friction increases linearly with each group of turns, thus radial expansion is easily accomplished in a controlled manner. FIG. 2 shows a typical balloon 7 such as commonly used for angioplasty disposed within stent 1, the balloon 7 being in its deflated condition. The reversing loops 6 of stent 1 are lightly crimped so that they grip the balloon to provide enough friction to prevent stent 1 from sliding and slipping off the balloon 7 during transportation and deployment.

An alternate method to produce the stent is to wind the wire directly over the balloon, in which case the balloon itself becomes the mandrel. In this preferred method, the tightness of the stent over the balloon is better controlled and the assembly is controlled by the manufacturer assuring proper quality. Reversing loops 6 are circumferentially skewed and angularly displaced from one another with respect to the linear axis of the stent so as not to be in line in order to avoid a seam effect, and to provide a better balanced support. At the same time the non-alignment of loops 6 permits more uniform flexing of the stent during deployment, to follow the natural bends within the cardiovascular system, and especially after expansion and implantation to provide even and free flexing with natural body movements.

An object of this invention is the provision of a coiled wire stent which allows easy expansion and subsequent retention of the expanded shape within the vessel.

Still another object of this invention is the simplicity of its application, especially with respect to angioplasty, where one single procedure accomplishes two distinct functions. The stent being initially placed and fitted over the balloon is expanded at the same time and by the action of inflation of the balloon, where the first function is to compress the plaque, thus creating a recanalized lumen as characterized by angioplasty, and the second function is to deploy and anchor a permanent stent prosthesis within the newly created recanalized lumen to prevent reclosure, restenosis and to maintain a free flow of blood indefinately. Both of these functions are accomplished simultaneously and with a single insertion of the catheter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation of a preferred embodiment of a stent according to this invention;

FIG. 2 is a side elevation showing an overall view of a stent prosthesis fitted over a deflated balloon prior to insertion;

FIG. 3 shows the balloon and stent assembly advanced within a vessel, approaching a partial occlusion;

FIG. 4 is similar to FIG. 3 showing the balloon and stent assembly inside a partially obstructed vessel;

FIG. 5 is similar to FIG. 4, the balloon shown inflated, and the stent radially expanded, illustrating the preferred method of an angioplasty procedure coupled with a simultaneous deployment and implantation of a permanent prosthesis stent; and

FIG. 6 is a view similar to FIG. 5 showing the prosthesis stent implanted and plaque compressed and retained, after removal of the balloon.

DESCRIPTION OF THE PREFERRED EMBODYMENT

For purposes of better and clearer understanding of this invention reference is made to FIGS. 1-6. The preferred embodiment of this invention is shown and described in an application for angioplasty; however, it is understood that other applications not specifically mentioned herein are possible and no limitations in scope of this invention are intended or implied without departing from the basic principles of this invention.

FIG. 1 shows the details of construction of the prosthesis stent 1, hereafter called the stent, which is basically of a hollow cylindrical shape. Stent 1 is basically a tubular shape of coiled wire wound in a special manner comprising a number of groups of turns 2. The wire is made of drawn low memory level material such as copper alloy 110 titanium ASTM F63-83 Grade 1 or gold K 19-22. In the case of copper, the wire is coated with biologically compatible polyester or Teflon. Titanium or gold are biologically inert, therefore those skilled in the art need no further description.

In FIG. 2 it is shown, that the stent 1 is centrally located and positioned with respect to length of balloon 7, and that individual coils are evenly spaced so that when expanded, the stent 1 will provide an even support inside the vessel 8 (FIG. 3) and be able to resist external loading.

In FIG. 3 it is shown how the stent 1 fitted over the balloon 7 emanates from from a guiding catheter 9 inside vessel 8 and is advanced toward partial occlusion 10. In FIG. 4 it is shown how balloon 7 and stent 1 are located inside occlusion 10 within artery 8, balloon 7 still being in a deflated and low profile condition. Once positively located inside occlusion 10, balloon 7 is inflated using standard angioplasty procedures and techniques. As balloon 7 expands so does the stent 1, as shown in FIG. 5. The expanding balloon 7 causes plaque 11 to compress, while simultaneously expanding stent 1 follows and supports and contains the plaque 11 preventing the plaque from again reoccluding vessel 8.

Angioplasty procedure now completed, balloon 7 is deflated and withdrawn leaving stent 1 firmly implanted within vessel 8. The previously occluded part 10 of vessel 8 is now positively recanalized and complete patency restored. FIG. 6 shows stent 1 firmly implanted and imbedded in compressed plaque 11, providing both an adequate support as well as a smooth lumen void of protrusions, a very desireable condition, since any protrusions are conducive to turbulant flow of blood and potential formation of thrombosis.

To test the viability of the principle of this invention, a polyester-coated copper wire approx. 0.009" dia. was wound on a mandrel 0.063" dia. in a manner described earlier with 4 turns wound CW then reversed and 4 turns CCW, and so on. This wire wound form was then

removed from the mandrel and placed over a 3.5 mm balloon type LP DILACA, and the balloon subsequently inflated using air and a standard 10 cc disposable syringe. It was observed that liquid, such as plain water, was a better inflating medium than air and so it was used for subsequent tests all with acceptable results. Various sizes of wire and different materials were used to determine optimum combinations. To simulate clinical conditions, and to observe the mode of expansion of the stent inside a vessel, a model stent was made of 0.008" dia. copper wire, and placed over a 3.5 mm balloon, and the assembly was inserted inside a Latex tubing 2.5 mm inside diameter and 0.8 mm wall. The balloon was inflated and expansion of the stent was observed through the translucent wall of the tubing while it progressed as intended. Deflating the balloon left the stent firmly implanted inside the experimental Latex tubing. Further experiments showed that multiple stents can be used. In fact, a typical balloon as shown in FIG. 2 fitted with a stent can be fed through a previously expanded stent, said second stent being placed ahead of said first stent for multiple implants.

Clinical tests on animals are presently being conducted, and initial results are very encouraging and promising.

While this invention described and illustrated herein depicts a typical application for coronary implant, it is to be understood that the above is considered to be of illustrative and non-restrictive character, since similar procedures and techniques can be applied to several other applications and uses without departing from the basic scope and spirit of this invention.

I claim:

1. A radially expandable stent for implantation within a body vessel, comprising

a wire winding in a hollow cylindrical shape,

the winding including a series of groups of helical coils along the length of the winding for providing radial strength,

the coils of each group being wound in a direction opposite to the direction of winding of the next adjacent group of coils,

a reversely-turned loop joining each two successive groups of coils for allowing smooth expansion of the adjacent groups of coils, and

means within the wire winding for expanding the winding.

2. A stent as defined in claim 1 wherein each reversely-turned loop is angularly spaced from every other reversely-turned loop of the stent.

3. A stent as defined in claim 1 wherein the unexpanded stent has an outside diameter less than 0.075 inch.

4. A stent as defined in claim 1 wherein the stent is radially expandable to approximately three times its original diameter.

5. A stent as defined in claim 4 wherein in its expanded condition, each group of coils includes at least one full coil.

6. A stent as defined in claim 1 wherein said expanding means is an expandable balloon extending longitudinally within the winding.

7. A stent as defined in claim 6 wherein at least some of the reversely-turned loops are bent toward the axis of the stent so that they tend to grip the balloon.

8. A method of treating a body vessel, comprising the steps of:

providing a stent wound wire having a hollow cylindrical shape, the stent being radially expandable and having the ability to retain its shape after expansion,

providing a balloon within the stent, the balloon being at least partially deflated,

inserting the stent and balloon into a body vessel having at least a partial occlusion and then along the vessel until they reach the occlusion,

expanding the balloon so as to expand the stent against the inner surface of the vessel to open the occlusion and simultaneously expand the stent, and

deflating and removing the balloon while leaving the expanded stent in place.

9. A method as defined in claim 8 including the step of inserting a second stent and a balloon within it through a first expanded stent, and expanding the balloon and second stent at a point longitudinally offset from the first stent.

10. A radial expandable stent for implantation within a body vessel comprising:

a stent body having a hollow cylindrical shape, the body including multiple helical coils along the length of the body, each coil including at least one complete turn,

the turns of each coil being wound in a direction opposite to the direction of winding of the adjacent coils, and

means for connecting the helical coils.

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